Dissertation on

PROSPECTIVE, RANDOMISED COMPARISON STUDY OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAYS, PROSEAL LMA AND I-GEL IN ELECTIVE SURGERIES

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CERTIFICATE

This is to certify that the dissertation entitled, **"Prospective, randomised comparison study of clinical performance of two supraglottic airways, PROSEAL LMA and I-GEL in elective surgeries".** Submitted by **Dr. S. RAJKUMAR** in partial fulfillment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai is a bonafide record of the work done by him in the Institute of Anaesthesiology & Critical Care, Madras Medical College, during the academic year 2008-2011

PROF .Dr.C.R.KANYAKUMARI, MD,DA
DIRECTOR AND PROFESSOR
INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE
MADRAS MEDICAL COLLEGE
CHENNAI-600003

GUIDE PROF.DR.R.RAJENDRAN, MD, DA
DEPT. OF ANAESTHESIOLOGY
INSTITUTE OF OBSTETRICS AND GYNECOLOGY
EGMORE CHENNAI

DR.J.MOHANASUNDARAM,MD,DNB,PhD
DEAN
MADRAS MEDICAL COLLEGE&
GENERAL HOSPITAL
CHENNAI

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CONTENT

INTRODUCTION

The laryngeal mask airway has gained recognition as an acceptable device for securing the airway of patients during anaesthesia and emergency airway management within the hospital environment. Furthermore, the LMA has been utilized by paramedics in the pre-hospital setting when endotracheal intubation is either unavailable (untrained personnel) or impossible (failed intubation).

The LMA revolutionized the anaesthetic practice and has now been used in more than 80 countries throughout the world .the LMA has been widely accepted as a form of airway management in the pre-hospital environment and inexperienced personnel. It has been shown that insertion of the LMA is easier and is less likely to produce gastric insufflations , a common problem with face mask ventilation. The LMA has now been referred to as gold standard of supraglottic devices.

The inventor of the “classic LMA” , Dr Archie Brain ,devised the airway to provide an alternative to the face mask ventilation. The LMA offers a relatively “hand-free’ airway that does not require laryngoscopy for insertion and thereby minimizing laryngeal trauma and unwanted laryngeal reflexes.

For these reasons, the LMA is endorsed by the Australian resuscitation council and The American Society Of Anaesthesiologists as

rescue airway, and as a first line airway management device in those with limited airway management experience.

It does not provide airway protection in full stomach patients and it increases chances of aspiration. To overcome the above complications Dr Archie Brain designed the Pro-seal LMA in 2000,with modification designed to enable separation of GIT and respiratory tract, to improve airway seal, to enable positive pressure ventilation and diagnose mask displacement. A drainage tube enables diagnosis of mask displacement; reduce the risk of gastric insufflations, regurgitation and aspiration of gastric content.

I-gel is a new supraglotic device .I-gel has successfully combined the concept of non cuffed supraglottic device like SLIPA and the gastric tube of the ProSeal LMA, yet retaining the shape LMA. This will also, reduce the risk of gastric insufflations, regurgitation and aspiration of gastric contents.

With this background this study was conceptualized to compare clinical performance of I-gel and ProSeal LMA in elective gynecological surgeries.

AIMS AND OBJECTIVES

The purpose of this study was to prospectively compare the clinical performance of the two supraglottic airway devices, PROSEAL LMA AND IGEL in elective surgeries in terms of the following parameters.

1. Ease of insertion
2. No. of insertion attempts
3. Time taken for insertion
4. Hemodynamic responses
5. Blood staining of devices
6. Incidence of complication

STRUCTURE AND FUNCTION

OF UPPER AIRWAY

STRUCTURE AND FUNCTION OF THE UPPER AIRWAYS[10]

Anatomically airway is the passage through which the air passes during respiration. It may be divided into upper and lower airway. The upper airway comprises nasal cavity, oral cavity, nasopharynx, oropharynx, pharynx and larynx.

Nasal cavity:

Nasal cavity extends form nares to end of the turbinates. The normal airway begins functionally at the nares. As air passes through the nose, the important functions of warming and humidification occur. The nose is the primary pathway of normal breathing. The nasal cavities are divided by nasal septum. The roof is formed by cribriform plate of the ethmoid bone. The bony lateral wall is the origin of the three bony turbinates that project into the nasal cavity. Openings in the lateral wall communicate with paranasal sinuses.

Oral cavity:

It extends from mouth opening to anterior tonsillar pillar. Contracture of mouth and lips can lead to difficult laryngoscopy. The roof of the mouth is bounded by alveolar arch and teeth and consist of the hard palate anteriorly and soft palate posteriorly. The tongue makes up most of the mouth, which is bounded by the mandible and teeth. The ability to

achieve good mouth opening is important for many airway procedures. Initial mouth opening is achieved by rotation within the temperomandibular joint and subsequent opening by sliding of the condyles of the mandible within the joint.

Pharynx:

The Pharynx is a fibromuscular tube that extends from the base of the skull to the lower border of cricoid cartilage. It joins the nasal and oral cavities above; with larynx and esophageus below. It is divided into nasopharynx and oropharynx.

The nasopharynx:

Extends from the posterior end of turbinates to posterior pharyngeal wall above the soft palate and consist of the nasal cavity, septum, turbinates and adenoids.

The oropharynx:

Extends from the soft palate above and epiglottis below; and anteriorly from tonsillar pillar to posterior pharyngeal wall. It includes the tonsils, uvula and the epiglottis. The tongue is the principal source of oropharyngeal construction, usually because of decreased tone of the genioglossus muscle. The latter contracts to move the tongue forward during inspiration and thus acts as a pharyngeal dilator. The vallecula is

the space between epiglottis and base of the tongue. It has paired depressions on both sides of glosso epiglottic fold.

Laryngoscope blade tip is positioned in vallecula during conventional laryngoscopy. Gentle upward pressure on the vallecula with laryngoscope blade tensions hyoepiglottic ligament and indirectly elevates the larynx and helps in the alignment of laryngeal and pharyngeal axes.

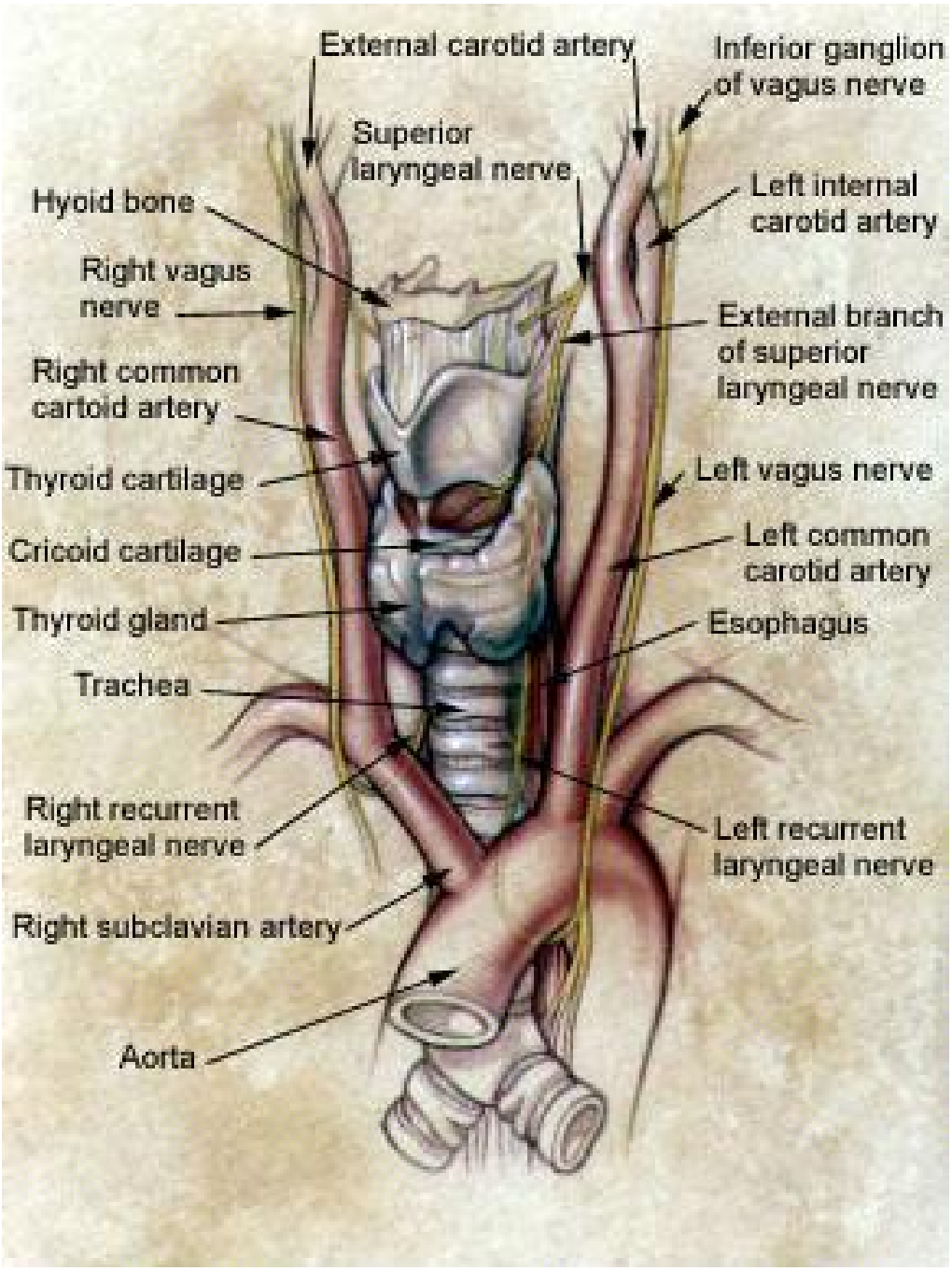
Larynx:

The larynx, which lies at the level of the third through sixth cervical vertebrae, serves as the organ of phonation and as a valve to protect the lower airways from the contents of the alimentary tract.

The laryngeal cavity extends from the epiglottis to the lower level of the cricoids cartilage. The larynx bulges posteriorly into the laryngopharynx, with the pyriform fossa lying on each side. It is suspended from the hyoid bone by the thyrohyoid membrane.

The structure consists of muscles, ligaments, and a framework of cartilages. These include the thyroid, cricoids, arytenoids, corniculates, and the epiglottis. The latter, a fibrous cartilage, has a mucous membrane covering that reflects as the glossoepiglottic fold onto the pharyngeal surface of the tongue. The epiglottis projects into the pharynx and

ANATOMY & NERVE SUPPLY OF LARYNX



overhangs the laryngeal inlet. However, it is not absolutely essential for sealing off the airway during swallowing.

The inlet is formed by the epiglottis, which joints to the apex of the arytenoid cartilages on each side by the aryepiglottic folds. Inside the laryngeal cavity one first encounters the vestibular folds, which are narrow bands of fibrous tissue on each side. These extend from the anterolateral surface of each arytenoids to the angle of the thyroid where the latter attaches to the epiglottis. These folds are referred to as the false vocal cords and are separated from the true vocal cords by the laryngeal sinus or ventricle.

The true vocal cords are pale white ligamentous structures that attach to the angles of the thyroid anteriorly and to the arytenoids posteriorly. The triangular fissure between these vocal cords is termed the glottis opening, which represents the narrowest segment of the laryngeal opening in adults.

Cricoid cartilage is a complete ring shaped cartilage and continues with trachea. In young children (<10 years old), the narrowest segment lies just below the cords at the level of the cricoid ring.

LARYNGEAL MASK AIRWAY

CONCEPTS AND DESIGNS OF LMA

The LMA fills a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. It is manufactured from medical grade silicone rubber and is reusable. It consists of 3 main components – Airway tube, inflatable masks and mask inflation line .

The airway tube is slightly curved to match the oropharyngeal anatomy, semi rigid to facilitate atraumatic insertion and semi transparent, so that condensation and regurgitated material is visible. A black line runs longitudinally along its posterior curvature to aid in insertion.

The distal inflatable mask is protected by two flexible vertical rubber bars, called mask aperture bars, to prevent the epiglottis from entering and obstructing the airway. The inflatable mask is oval shaped with a broad, round proximal end and a narrower, more pointed distal end. It has an inflatable cuff and a semi rigid, concave, shield like back plate.

The inner aspect of the mask is called the bowl, which is comprised of the distal aperture, mask aperture bars, back plate and the inner aspect

of the inflatable cuff. The LMA consists of a curved tube (shaft) connected to an elliptical spoon shaped mask at an angle of thirty (30) degrees.

At the machine end of the tube is a standard 15mm connector

There are 7 available sizes. The selection of size is according to the body weight of the patient and cuff volume is specified for each size, shown in the following table

Mask size	**Body weight (kg)**	**Maximum inflation volume (ml)**
1	< 5	4
1	5 – 10	7
2	10 – 20	10
2.5	20 – 30	14
3	30 – 50	20
4	50 – 70	30
5	> 70	40

INDICATIONS OF LMA

1. LMA is used for securing patient's airway during general anaesthesia as an alternative to endotracheal tube or face mask
2. LMA is useful in patients where maintenance of airway with mask is difficult such as edentulous patients, facial injury, burns

3. In case of inability to intubate or ventilate LMA may be life saving either as primary means of securing patient's airway or to facilitate passage of ET tube
4. LMA can be used for diagnostic bronchoscopy as an excellent aid to laryngeal inlet
5. During CPR, for rapid securing of patient's airway, LMA can be used

CONTRAINDICATIONS :

1. Patients with full stomach
2. Patients with hiatus hernia unless effective measures have been taken to empty the stomach
3. Patients with fixed reduced pulmonary compliance such as pulmonary fibrosis
4. Oral, perioral pathology such as tumour, abscess, grossly enlarged tonsil
5. Mouth opening less than 2cms

ADVANTAGES OF LMA OVER ENDOTRACHEAL TUBES:

1. Rapid and easy access of airway
2. Laryngoscopy and muscle relaxants are not required

1. Hemodynamics and intraocular pressure changes are less than endotracheal tube intubation

2. Tolerance is better and LMA is less likely to cause injury to the airway than endotracheal tube

3. Minimal stimulation if left in situ until protective airway reflexes are recovered

ADVANTAGES OF LMA OVER FACE MASK :

1. It is easier to obtain air tight seal with LMA when a good seal with face mask is difficult

2. The anaesthesiologist's hands are free and does not require jaw support

DISADVANTAGES OF LARYNGEAL MASK AIRWAY:

1. Patient with glottis or subglottic obstruction cannot be managed with LMA

2. Appropriate size LMA should be used. Larger or smaller size LMA will result in improper seating, leading to cuff leak or airway obstruction due to trapping of epiglottis

1. The airway is not protected. Hence LMA is not to be used in patients with full stomach

TYPES OF LMA

- Reinforced / flexible LMA (LMA – flexible)
- LMA specifically designed for tracheal intubation (LMA – Fastrach)
- Intubating LMA with real time visualization of larynx (LMA-C Trach)
- Single – use LMA (LMA – Unique)
- LMA with an integral gastric access venting port (LMA – Proseal)

PROSEAL LMA[9]

The Proseal laryngeal mask airway was designed and developed by Dr.Archie Brain in late 1990, with a primary goal to construct a laryngeal mask with improved ventilatory characteristics and that also offered protection against regurgitation and gastric insufflations.

DEVICE DESCRIPTION:

The Proseal LMA is made from medical grade silicone and is reusable. It has four main components

1. Mask
2. inflation line with pilot balloon
3. Airway tube
4. Drain tube

The cuff of the mask has identical proportions but different dimensions amongst sizes.

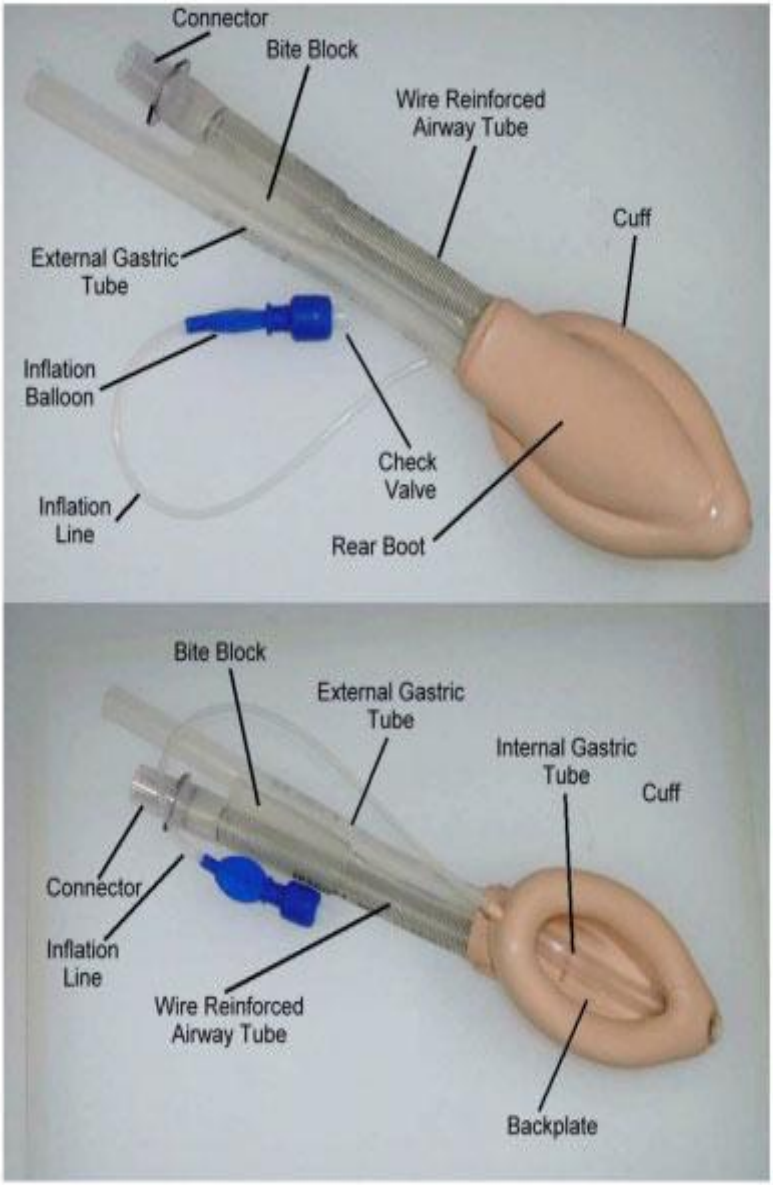
Modified Feature	**Intended Purpose**
1) The second cuff attached to dorsal surface	To improve seal by pushing the ventral cuff
2) The ventral cuff that is larger proximally	To form a better seal by plugging gaps in the proximal pharynx To reduce the risk of down folded epiglottis obstructing the distal aperture

3) A large conical shaped distal Cuff	To form a better seal with the hypopharynx. To reduce the risk of down folded epiglottis obstructing the distal aperture
4) A parallel, narrow – bore, double tube configuration	To increase stability To improve seal by allowing the tongue to form a more effective plug
5) A flexible, wire reinforced airway tube	To prevent airway tube from kinking
6) A drainage channel	To facilitate gastric tube insertion To divert regurgitated fluid away from the respiratory tract. To prevent gastric insufflation
7) A drainage tube distal aperture that is sloped anteriorly	To allow the deflated tip to form a fine edge for insertion
8) A plastic supporting ring around the distal drainage tube	To prevent the drainage tube from collapsing when the cuff is inflated
9) Drainage tube that passes within the bowel	To avoid altering the external shape of the cuff To function as mark aperture bar for accessory vent
10) A rectangular depression in the proximal bowel tube	To function as an accessory ventilation channel To prevent pooling of secretions at the distal aperture of the airway

11) Built – in – bite block	To prevent airway obstruction To prevent damage to the device during biting To provide information about depth of insertion To help fuse airway and drainage tube together
12) Introducer strap	To prevent finger from slipping off the tube To keep proximal cuff in the midline
13) No back plate	To reduce and allow room for the dorsal cuff
14) No mask aperture bar	To reduce resistance to gas flow

SIZES AVAILABLE

Proseal LMA size	***Patient selection Guidelines***	***Proseal LMA airway tube ID(mm)***	***Maximum cuff inflation Volume (Air)***	***Gastric Tube***	***ETT***	***FOD***
1 ½	5 – 10 kg	6.4	7ml	10 Fr	4.5	3.5
2	10 – 20 kg	6.4	10ml	10 Fr	4.5	3.5
2 ½	20 – 30 kg	8.0	14ml	14 Fr	4.5	3.5
3	30 – 50 kg	9.0	20ml	16 Fr	5.0	4.0
4	50 – 70 kg	9.0	30ml	16 Fr	5.0	4.0
5	70 – 100 kg	10.0	40ml	18 Fr	5.0	4.0


Connector
Bite Block
Wire Reinforced
Airway Tube
Cuff
External Gastric
Tube
Inflation
Balloon
Check
Valve
Inflation
Line
Rear Boot
Bite Block
External Gastric
Tube
Internal Gastric
Tube
Cuff
Connector
Inflation
Line
Wire Reinforced
Airway Tube
Backplate

These are maximum volumes that should never be exceeded. It is recommended that the intracuff pressure should not exceed 60cm H2O.

Protocol for PLMA Use:

Preparation of Use :

With proper cleaning, sterilization and handling, the proseal LMA can be safely used 40 times

CLEANING :

It is washed in warm water and dilute (8 -10% w/w) sodium bicarbonate solution until all visible foreign matter is removed. Clean the tubes using a small soft bristle brush. Thoroughly rinse the cuff, airway tube and drain tube in warm, flowing tap water to remove cleaning residues. Care should be taken to ensure that water does not enter the device through the valve.

STERILIZATION :

Steam autoclaving is the only recommended method for sterilization of the proseal LMA. Immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backwards to obtain a high vaccum.

The maximum temperature should not exceed 135^0 C or 275^0 F. The proseal LMA introducer and cuff deflator should be cleaned and sterilized in the same manner.

PERFORMANCE TESTS :

Non – clinical tests must be conducted before each use of the device. These include,

1. Visual inspection :

Ensure that the thin- walled section of the drain tube lying within the mask bowl is not torn or perforated. Do not use the proseal LMA if the tubes are discoloured as this impairs the ability to see foreign particles or regurgitated fluids. Examine the surface of the device for damage.

2. Inflation and deflation :

Using a syringe fully deflate the device so that the cuff walls are tightly flattened against each other. Do not use if the cuff walls re-inflate immediately and spontaneously

INDEX FINGER INSERTION TECHNIQUE

- Finger insertion technique is not recommended for proseal LMA sizes 1 ½ - 2 1/2 . These sizes have a dedicated introducer

- Hold the proseal LMA like a pen with the index finger pushed into the introducer step
- Under direct vision, press tip of the cuff upwards against the hard palate and flatten the cuff against it.
- As the index finger passes further into the mouth finger, joint begins to extend
- The jaws should not be held widely open
- Push the downwards with middle finger or instruct the assistant to pull lower jaw downwards momentarily using the index finger to guide the device, press downwards towards the other hand, exerting counter pressure
- Advance the device into hypopharynx until a definite resistance is felt. Full insertion is not possible unless the finger is fully extended and wrist is fully flexed
- Before removing the finger, the non dominant hand is brought from behind the patients head to press down on the airway tube
- This prevents the device from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point the proseal LMA should be correctly located with its tip firmly pressed up against the upper oesophageal sphincter. Remove the finger

DEVICE INFLATION

After insertion, the tubes should emerge from the mouth directed caudally. Without holding the tubes, inflate the cuff with just enough air to obtain an intracuff pressure equivalent to approximately 60cm H2O. During cuff inflation, do not hold the tube as this prevents the mask from settling into its correct location.

The signs of correct placement may include one or more of the following

- Slight outward movement of tube upon inflation
- Presence of smooth oval swelling in the neck around the thyroid and cricoid area. Never over inflate the cuff
- Expansion of the chest wall on bag compression
- The conformation of the correct placement by square wave pattern in capnography.

DEVICE FIXATION :

Once inflated, the device should be fixed in place with fish mouth taping (maxilla to maxilla. While fixing, ensure that the tip of the mask is pressed securely against the upper oesophageal sphincter. Correct fixation is more critical for PLMA because any migration proximally of the tip from hypopharynx will result in air leakage up the DT during IPPV.

OROGASTRIC TUBE INSERTION :

The primary function of the drain tube is to provide a separate conduit from and to the alimentary tract. This is then passed down the DT of PLMA without any haste or force. A slight resistance is normal felt as the tip passes against upper oesophageal sphincter.

There is an inherent resistance to gastric tube insertion after 23cm of passage due to angulation of 9^0 in the passage of DT to its tip. There may be difficulty in passing gastric tube due to following reasons

1. Selection of too large gastric tube
2. Inadequate lubrication
3. Use of cooled gastric tube
4. Cuff over inflation
5. Malposition of PLMA

The advantages of inserting gastric tube are

1. It allows removal of gas or fluid from the stomach
2. Confirm position / Patency of drainage tube
3. Functions as a guide to PLMA insertion if accidental displacement occurs

The disadvantages of inserting gastric tube are

1. Risk of tracheal placement
2. Oesophageal perforation rarely
3. The presence of gastric tube may trigger regurgitation by interfering with oesophageal sphincter function
4. Gastric tube blocks drainage tube so that gas and fluid cannot escape from oesophagus

I –GEL

I – gel is the new Supraglottic airway device developed by Intersurgical Ltd., (Workingham, Berkshire, UK). It is made up of medical grade thermoplastic elastomer, which is soft, gel like transparent & designed to anatomically fit the perilaryngeal & hypopharyngeal structures without an inflatable cuff. It is said to have easier insertion, minimal risk of tissue compression & stability. It is latex free supraglottic device. It is available in seven variable sizes 1, 1.5, 2, 2.5, 3, 4, 5.

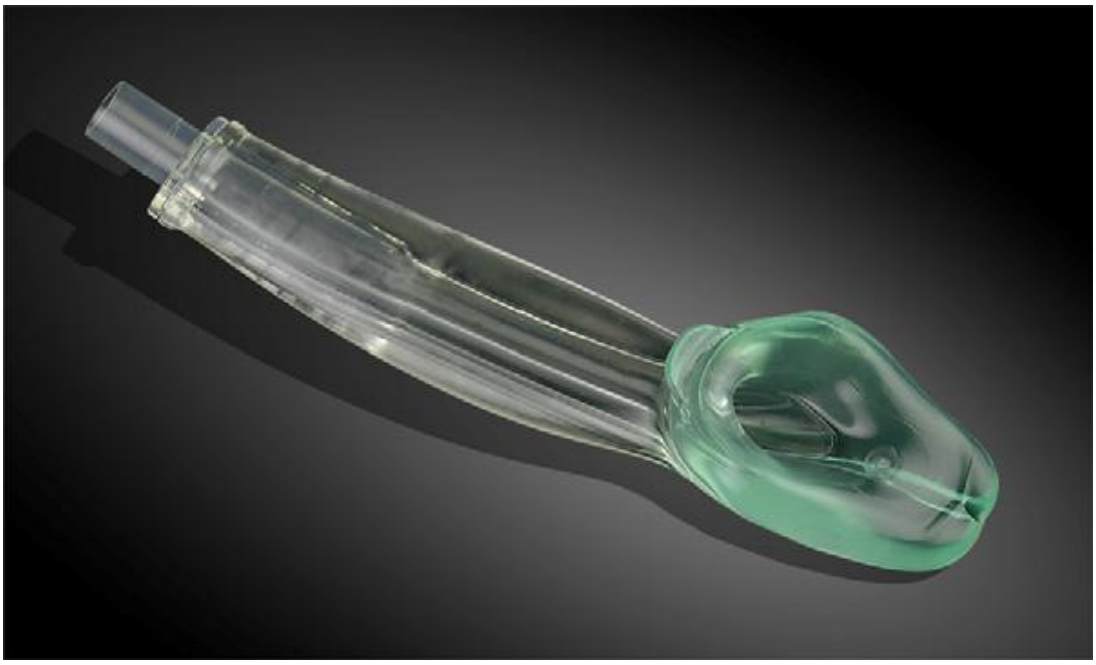
KEY COMPONENTS AND THEIR FUNCTION

1. Soft non inflatable cuff

The novel soft noninflatable cuff fits snuggly on to the perilaryngeal framework. The tip lies in the proximal opening of the esophagus isolating theesophageal opening from the laryngeal inlet. The outer cuff shape ensures that the blood flow to the laryngeal and perilaryngeal framework is maintained and helps to reduce the possibility of neurovascular compression.

2. Gastric channel

The gastric channelruns through a device from its proximal opening at the side of the flat connector wing to the distal tip of the non inflatable cuff. Since the distal part of the device fits snuggly and



anatomically correctly into the upper esophageal opening. The distal opening of the gastric channel allows for the passing of a nasogastric tube to empty the stomach contents and can facilitate the venting of the gas from stomach. The size one I gel does not have gastric channel

3. Epiglottic rest

An artificial epiglottis and a protective ridge help prevent the epiglottis from downfolding or obstructing a distal opening of the airway

4. Buccal cavity stabilizer

The buccal cavity stabilizer has a built in natural curvature and an inherent propensity to adapt its shape to the oropharyngeal curvature of the patient. It is anatomically widened and concaved to eliminate the potential for rotation, thereby reducing the risk of mal rotation.

5. 15mm connector

To provide a standard 15mm connection to the anaesthetic system.

A port of entry for gastric channel – the port is independent of the main 15 mm connection and is located on the right side of the connector wing

Integral bite block – this function is provided by the distal part of the connector which runs through the centre of the proximal part of the buccal cavity stabilizer

As a guide to correct positioning – the integral part of the bite block is marked with a horizontally placed black line which signifies the optimum position of the teeth while the device is in situ

INSERTION TECHNIQUE

1. The patient should be in the sniffing position . The chin should be gently pressed down before proceeding to insert I gel

2. Grasp the lubricated I gel firmly along the integral bite block. Position the device so that I gel cuff outlet is facing towards the chin of the patient

3. Introduce the leading soft tip into the mouth of the patient in a direction towards the hard palate.

4. Glide the device downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance is felt.

5. At this point the tip of the airway should be located into the upper esophageal opening and the cuff should be located against the laryngeal framework. The incisors should be resting on the integral bite block

6. The I gel should be taped down from maxilla to maxilla

7. An appropriate size nasogastric tube passed down the gastric channel.

REVIEW OF LITERATURE

ISHWAR SINGH, MONIKA GUPTA, MANSI TANDON[1]

(Indian journal of anaesthesia 2009:53(3):302-305)

They compared I gel and proseal LMA in elective surgeries. They assessed the airway sealing pressure, ease of insertion ,success rate of insertion, use of gastric tube placement , airway trauma by post operative blood staining of the device ,tongue, lip, and dental trauma, hoarseness ,regurgitation-aspiration and cost effectiveness.

They found airway sealing pressure was higher with group p(29.6 CM H_2O) than group i(25.27 CM H_2O ($p<0.05$)) but the airway sealing pressure of group I was very well within the normal limit to prevent the aspiration. The ease of insertion was more with group I(29/30) than with group p(25/30) the success rate of first attempt of insertion and ease of gastric tube placement was more with group I($p>0.05$).blood staining of device and tongue lip dental trauma was more with group p($p>0.05$). there was no evidence of bronchospasm, laryngospasm, regurgitation, aspiration or hoarseness in either group.

J.J GATWARD, T.M.COOK, C.SELLER

(Anaesthesia , 2008,63 pages 1124-1130).

They studied the I-GEL in 100 elective, anaesthesised patients (55 male, 45 female, median age is 53 years) assessing ease of use, airway quality, positioning, seal and complications. First insertion attempts was successful in 86 patients, second attempt in 11 patients, third attempt in 3 patients. 53 manipulations were required 26 patients to achieve aclear airway. Median insertion time was 15 seconds. During ventilation expired tidal volume of 7 ml per kg was achieved in 96 patients. Median airway leak pressure was 24 CM H_2 O on fibro optic examination via the device vocal cord were visible in 87 patients. There one episode of regurgitation without aspiration. They found I-GEL was easily and rapidly inserted, providing a reliable airway in over 90% of patients.

V.UPPAL , S.GANGAIAH, G.FLECTHER AND J.KINSELLA

(British journal of anaesthesia 2009 feb :102(2):264-8)

They compared I-GEL and LMA in anaesthetized, paralyed adults. They assessed airway leak pressure, time to insertion, the number of insetion, and reposition attempts, leak volumes and leak fractions. They found there was no signifigance difference between the airway leak pressure of the two devices I-GEL and LMA respectively. The median insertion time for the I-GEL was signifigantly lesser than LMA-U. all the LMA-U devices 38 of 39 I-GEL airways wered inserted at the first

attempt. The number of manipulations required after insertion to scheive a clear airway was the same in both the groups(four in each). There were no statistically significant differences in leak volumes or leak fractions during controlled ventilation.

They found no difference in leak pressures and success rate of first time insertion between the I-GEL and the LMA-U. time to successful insertion was significantly shorter for the I-GEL. They concluded that the

I-GEL provides a reasonable alternative to the LMA-U for controlled ventilation.

SHIN.WJ, CHEONG YS. YANG HS[17]

European Journal of Anaesthesia 2009 Nov. 12

They compared IGEL, proseal LMA and classic LMA in anaesthetized patient. They assessed hemodynamic data, airway leak pressure, Leak volume, success rate and post operative complication. They found there were no difference in the demographic data and hemodynamic data immediately after insertion of the devices among three groups. The airway Leak pressure of the IGEL group (27.1$\pm$ 6.4cm H_20) and PLMA group (29.8 $\pm$ 5.7cm H_2O) were significantly higher than that of the cLMA group (24.7 $\pm$ 6.2cm H_2O) the success rate of insertion were similar among the three groups (P = 0.670).

There were no difference in the incidence of adverse events except for the large incidence of sorethroat in cLMA group. They concluded IGEL may have a similar airway sealing to that of PLMA higher than that of cLMA and not associated with adverse events.

HOHLRIEDER M, BRIMACOMBE J, VON GOEDECKE A[13], KELLER C et al IN 2007

Assessed postoperative nausea, vomiting, airway morbidity and analgesic requirements for PLMA and ETT in 200 female patients, ASA I & II, aged 18 – 75 yrs undergoing breast and gynaecological surgery.

Ventilation was better and airway trauma less frequent for PLMA. For PLMA time spent in postoperative care unit was shorter (69 Vs 88 mt $P<0.001$). Few doses of tropisetron ($P <$ or $=0.001$) required in postoperative care unit. Nausea was less frequent at all times (Over all 13% Vs 53%, $P = 0.001$) vomiting was less frequent at 2 hrs (4% Vs 18% $P = 0.003$) and 24 hrs (5% Vs 19%, $P = 0.004$) and sorethroat was less frequent at all times (Over all 12% Vs 38% $P < 0.0001$).

They concluded that the frequency of postoperative nausea, vomiting, airway morbidity and analgesic requirements are lower for PLMA when compared to endotracheal tube.

MILLER DM, COMPOROTA L[14], et al IN 2006

Compared the efficacy of PLMA and SLIPA supra laryngeal airways (SLA) with standard tracheal tube in 150 patient undergoing day care laparoscopic gynaecological surgery requiring general anaesthesia.

An identical GA technique was used in all patients apart from addition of muscle relaxants and reversal drugs in ETT group. Ease of use, quality of seal, ventilation, systolic pressure, response to intubation, side effects and operating room time were assessed.

Both PLMA and SLIPA were easy to insert (100% success) and ventilation with respective maximum sealing pressures of 31 and 30 cm H_2O (P = 0.4) with no muscle relaxants. The seal quality is both PLMA and SLIPA permitted the use of low flows, 485 (291) and 539 (344) ml x min (-1) (P = 0.2) respectively, although in the ETT group significantly lower flows (377 (124 ml x min (-1) (P < 0.01) were achieved.

Systolic pressure in the SLA group was more stable in response to insertion than in ETT gp with PLMA, there was a lower incidence of sorethroat than with ETT gp (30% Vs 57%) (P < 0.05) and less difference with SLIPA (30% Vs 49%) (P > 0.05).

With both SLA there was a significant reduction in operating room time (> 3 mts) (P <0.001).

The concluded that PLMA (reusable) and SLIPA (single use) SLA's were easy to use without requiring muscle relaxants and less operating room time compared to tracheal tube in day care laparoscopies.

PIPER SN, TRIEM JG, ROHM KD, MALECK WH, SCHOLLHORN TA, BOLDT J, et al IN 2004.

Assessed the practicality of PLMA when compared to ETT in 104 patients undergoing gynaecological laparoscopic surgery. TIVA was performed by the same anaesthetist. They measured MAP, HR, circuit pressure at 2 measurement points and incidence of coughing and sorethroat.

There was no difference between PLMA and ETT concerning circuit pressure at any measurement points. At the end of anaesthesia MAP (92 +/- 13 Vs 100 +/- 14 mmHg; $P < 0.001$) and HR (66 +/- 13 Vs 76 +/- 14 beats / mt; $P < 0.01$) were lower in the PLMA gp compared to ETT gp. 25 patients of ETT group coughed at the end of anaesthesia but nobody in PLMA group ($P < 0.00001$). there was no difference with regard to postoperative sorethroat. The insertion of PLMA was easier compared to ETT ($P < 0.05$), but they found no significant difference concerning insertion times.

Finally they concluded that PLMA is a convenient and practical approach for anaesthesia in patients undergoing laparoscopic surgery.

GIUSEPEE NATALINI MD, GABRIELLA LANZA MD, ANTONIO ROSANO MD[15], et al IN 2002.

Compared the frequency of airway seal and sorethroat with PLMA and std. LMA in 60 adults, ASA I, II & III patients undergoing lapraoscopic surgery under GA with controlled ventilation (Tidal volume 7ml/Kg, PEEP – 10 cm H_2O)

HR, BP, inspiratory and expiratory tidal volume, airway pressure, $EtCO_2$ and Sp O_2 were recorded. Leak fraction was calculated as the difference between inspiratory and expiratory tidal volume divided by inspiratory tidal volume. Postoperative sorethroat frequency was scored in the recovery room (early) and 1 week after surgery (Late).

Leak fraction was 7 $\pm$ 32% with LMA and 7 $\pm$ 4% with PLMA (P = 0.731). Frequency of sorethroat is mild in 13% and 10% of patients with LMA and PLMA respectively during the recovery room stay.

G.NATALINI, M.E. FRANCESCHETTI et al IN 2003

They compared PLMA with LMA in obese patients. The study was conducted on 60 obese patients randomized to receive mechanical ventilation through PLMA or LMA. Airway cuffs were inflated to 60cm H_2O. Controlled ventilation with 10cm H2o of PEEP with applied. If leak fraction was > 15% intra cuff volume needed to be increased in 45% of

patients in LMA group compared to 13% in PLMA group. Leak fraction in PLMA group was 6% which was comparable to tracheal group.

Hence they concluded that PLMA was a better airway device for morbidly obese patients compared to LMA.

DETAILS OF STUDY

1. OFFICIAL TITLE

"Prospective, randomised comparison study of clinical performance of two supraglottic airways, PROSEAL LMA and I-GEL in elective surgeries".

2. AIMS & OBJECTIVES

To compare the clinical performance of two supraglottic airways, PROSEAL LMA and I-GEL in elective surgeries".

3. STUDY DESIGN

Prospective, randomized, single blinded(subject), case control study

4. STUDY TYPE Interventional

5. STUDY SETTING AND POPULATION:

After obtaining institutional ethical committee clearance and patients written informed consent, the study was carried out in TOT, Institute of Obstetrics and Gyaecology, Egmore, Chennai, from may 2010 to July 2010.

The Study was conducted in 60 female patients in the age group of 18 years and above belonging to ASA I and II posted for elective gynaecological surgeries.

6. INCLUSION CRITERIA:

1. Age	:	18 Years and above
2. Weight	:	BMI < 30 Kg/m2
3. ASA	:	I & II
4. Surgery	:	Elective
5. Mouth Opening	:	> 3cm

7. EXCLUSION CRITERIA:

- ❖ Emergency Surgeries
- ❖ Age < 18
- ❖ Mouth opening < 3cm
- ❖ BMI > 30 Kg /M2
- ❖ Pregnant Female
- ❖ H/O. GERD
- ❖ Surgery involving upper GIT
- ❖ Poor lung compliance such as pulmonary fibrosis.

8. MATERIALS REQUIRED

- ❖ Proseal lma size 3
- ❖ I gel size 3
- ❖ 20ml syringe
- ❖ Lubricant jelly
- ❖ Drugs: Glycopyrolate, fortwin, propofol, midazolem, atracuriam, isoflourane, neostigmine, ranitidine, metaclopromide.
- ❖ Monitors: ECG, Pulse Oximeter, NIBP, Capnography.

9. STUDY OUTCOME

1. EASE OF INSERTION

Easy insertion(E): Defined as no resistance to insertion in the pharynx in a single attempt

Difficult insertion(D): Defined as the one in which there was resistance to insertion (or) more than one attempts was required

2. NO OF INSERTION ATTEMPTS

Insertion of the laryngeal mask followed a strict protocol, upto 3 attempts were made to insert the mask and the number of attempts required was recorded. An attempt was defined as one passage of the laryngeal mask into the oropharynx only. If unsuccessful after three attempts, the procedure abandoned.

3. TIME TAKEN FOR INSERTION

It was measured from proseal LMA or igel inserted into the patient oral cavity until conformation of the proper positioning of the airway.

4. HAEMODYNAMIC RESPONSES

The patient's pulse rate and blood pressure were recorded just before insertion and one minute and five minutes after the initiation of insertion attempts.

5. BLOOD STAINING OF DEVICES

At the end of the surgery the laryngeal mask removed, when the patient swallowing reflexes had returned and they could follow commands. The presence or absence of blood on the mask was noted.

6. INCIDENCE OF COMPLICATIONS

The patients were asked whether they had a sore throat after removal of LMA. The patients also carefully monitored whether they have any bronchospasm or laryngospasm.

METHODOLOGY

Ethical committee approval

↓

Patient satisfying inclusion criteria

↓

Informed consent obtained

↓

Randomization by closed envelope method

↓

I GEL group- PLMA group

↓

Premedication – inj. Glycopyrrolate 0.2mg + inj.Fortwin 30mg

Inj. Ranitidine 50mg + inj. Metaclopromide iv given.

↓

HR, BP Measured

↓

Preoxygenation for 3min

↓

Induction : inj. Propofol 2mg /Kg + inj Atracurium 0.5mg /Kg

↓

Pre insertion BP, HR measured

↓

Insertion

↓

Measurement of outcome : Ease of insertion , Time taken for insertion , No. of insertion attempts, Haemo dynamic response ,Blood staining of devices, Incidence of complication

↓

Surgery proceded with maintenance of Anaeshesia with N2O / O2

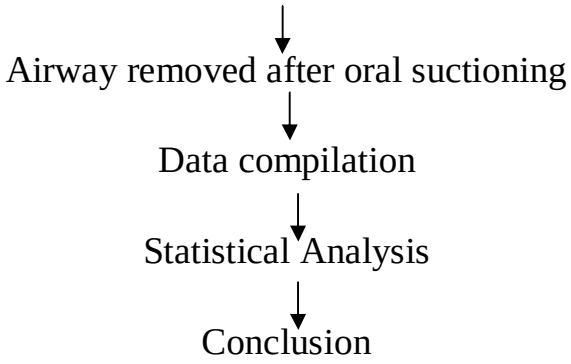
↓

mixture 2:1 +Iso fluorane 1MAC

↓

After Surgery patient

reversed with inj. Neostigmine 50micro gram/kg + inj. Glycopyrrolate 10 micro gram /kg



CONDUCT OF STUDY

The patients who had come for gynaecological surgery, screened for comorbid illness and difficult airway. Age, height, weight and BMI were assessed. If patients satisfied inclusion criteria, informed consent was obtained and the patients were randamised into two groups using closed envelope technique as proseal LMA group (P) and Igel group(I). After the patient was shifted inside the operation room, intravenous access gained. ECG monitor, pulsoximeter and non invasive blood pressure monitor were connected. Preoperative BP, Heart rate were recorded.

PREMEDICATION

Patient was premedicated with inj. Glycopyrrolate 0.2 mg, inj. Fortwine 0.5 mg/kg, inj. Ranitidine 50 mg and inj. Metaclopramide 10 mg.

PREOXYGENATION

Patient preoxygenated with 100% O_2 for 3 minutes.

INDUCTION

Patient was induced with inj. Propofol 2mg/kg and inj. Atracurium 0.5mg/kg. Patient was mask ventilated for 3 minutes. Pre insertion BP, Heart rate were recorded.

INSERTION

'P' Group

Size 3 proseal LMA was inserted in sniffing position by using Index finger insertion technique. Cuff was inflated with 20ml of room air to the manufacturer recommended cuff pressure of 60cm H_2O before anaesthetic circuit was connected and patients lung ventilated. Position of PLMA was confirmed by

1. Bilateral chest movement
2. Square $EtCO_2$ waveform
3. Absence of leak

With the PLMA, we filled the proximal 3cm of the drain tube with the water soluble lubricant jelly. If a gas bubble rose through the jelly during inspiration indicating a gas leak into the oesophagus. We corrected the position of PLMA and repeated the test until no bubble appeared.

'I' Group

Size 3 Igel was inserted in sniffing position. Position of Igel was confirmed by

1. Bilateral chest movement
2. Square $EtCO_2$ waveform
3. Absence of leak

PARAMETERS OBSERVED

1. Ease of insertion
2. No. of insertion attempts
3. Time taken for insertion
4. Hemodynamic responses
5. Blood staining of devices
6. Incidence of complications

MAINTANENCE OF ANAESTHESIA

Anaesthesia maintained with N20:O2 at 2:1 ratio and 1 MAC of isoflurane. Muscle relaxant was maintained with inj. Atracurium. Post

insertion BP, HR were recorded at 1 min and 5 minutes after insertion of supraglottic airways. Ryles tube was inserted through drainage tube. Gynaecologist was requested to initiate the surgical procedure.

REVERSAL & EXTUBATION

After completion of surgery and adequate neuromuscular recovery, patient was reversed with inj. Neostigmine 50 microgram/kg, inj. Glycopyrrolate 0.4 mg/kg. Suctioning of gastric content through ryles tube was done. After thorough oral suction, cuff was deflated and supraglottic airways were removed.

Blood staining in the airway devices, cough, laryngospasm/stridor, sorethroat and need for airway intervention during emergence from anaesthesia were recorded.

Once the recovery was found adequate, the patient was shifted to post operative ward and patients were interviewed for next 24 hours regarding sore throat.

OBSERVATION AND RESULTS

This prospective randomized comparative single blinded case control study of clinical performance of two supraglottic airway devices, IGEL AND PROSEAL LMA in 60 adult women, ASA I AND II, aged 18 years and above undergoing elective gynaecologic surgery . All data were collected, tabulated and expressed as mean +/− standard deviation . Appropriate statistical analysis was conducted. All quantitative data were compared using chi-square test. P values were calculated for all test. A p values 0 to 0.01 was considered as 1 % significant , 0.011 to 0.05 was considered 5% significant , and >0.05 was considered as not significant.

The summated results represented below.

Table :1 Demographic profile : age

Group	N0 :	Mean	SD	P value
I GEL	30	31.20	9.353	0.460
PROSEAL	30	29.47	8.681	Not significant

The mean age of group IGEL is 31.20 and group PROSEAL is 29.47.The data statistically not significant (p >0.05) and this both groups are comparable in terms of age.

Table 2: Demographic profile : BMI

Group	N0 :	Mean	SD	P value
I GEL	30	21.54	2.0698	0.530
PROSEAL	30	21.25	1.4323	Not significant

The mean BMI of group IGEL is 21.54 and group PROSEAL is 21.25.The data statistically not significant (p >0.05) and this both groups are comparable in terms of BMI.

Table 3 : Ease of insertion

Group	NO;	Easy		Difficult		P value
		NO	%	NO	%	P= 0.038
I GEL	30	28	93.3	2	6.7	Significant
PROSEAL	30	22	73.3	8	26.7	

By using I GEL , 28 cases were inserted easily and 2 cases were inserted with difficulty .By using PROSEAL LMA 22cases were inserted easily and 8 cases were inserted with difficulty.

Qualitative data values are compared by chi-square test. Statistical analysis reveals P value is 0.038 which is significant at 5% level.

Table:4 No of attempts

Group	No	Success in			P Value
		Ist Attempt	IInd Attempt	IIIrd attempt	
I JEL	30	28	2	-	P= 0.12
PROSEAL	30	24	6		NON SIGNIFICANT

IGEL insertion was successful in 28/30 in first attempt while 2 patients required second attempt PROSEAL LMA insertion was successful in 24/30 in first attempt while 6 patients required second attempt . statistical analysis reveals P value of 0.129 .the two groups are statistically insignificant in no of attempts(P>0.05)

Table 5; Time taken for insertion

Group	NO	Mean	SD	P value
I GEL	30	16.20	5.327	P= 0.000
Proseal LMA	30	25.20	5.162	P value < .001

Time taken for insertion with I GEL is 16.20 seconds and PROSEAL LMA is 25.20 seconds. Student t test reveals P value of 0.000($p < 0.001$) which is significant at 1% level.

Table 6; Blood staining of devices.

Group	No	Blood Staining		P Value
		Yes	No	
I GEL	30	2	28	P=0.038 SIGNIFICANT
PRO SEAL	30	8	22	

Blood staining the airway device noted after removal of the device indicates airway trauma. It occurred in 2/30 cases with I GEL, 8/30 cases with PROSEAL LMA. Chi –square test reveals p value of 0.038 which significant at 5% level. Hence the incidence of airway trauma is low with I GEL.

Table No:7: Incidence of Complications

	Group	No	Yes	No	P Value
Sore Throat	I GEL	30	-	30	P=0.150 NOT SIGNIFICANT
	PRO SEAL	30	2	28	

	Group	No	Yes	No	P Value
Bronchospasm Laryngospasm Regurgitation	I GEL	30	-	30	P=1.00 NOT SIGNIFICANT
	PRO SEAL	30	-	30	

Intra & Post Operatively following complications were assessed. 1) Bronchospasm 2) Laryngospasm 3) Sore Throat 4) Regurgitation. Sore Throat assessed for 24hrs Post Operatively.

Sore Throat occurred in 2/30 cases with PRO SEAL LMA and no sore throat with I GEL. Statistical analysis reveals P Value of 0.150 which is Not Significant.

Laryngospasm, Bronchospasm & Regurgitation does not occur with both the groups. Stastical analysis reveals P Value of 1.000 which is Not Significant. Hence incidence of complications is same with both groups.

Table:8: Haemodynamic Response

Heart Rate

	Group	No	Mean	SD	P Value
Pre Insertion	I GEL	30	89	10.252	P=0.073 Not Significant
	PRO SEAL	30	83.47	13.038	
Post Insertion after 1 min	I GEL	30	95.43	10.311	P=0.353 Not Significant
	PRO SEAL	30	92.60	12.968	
Post Insertion after 5 min	I GEL	30	93.67	10.672	P=0.527 Not Significant
	PRO SEAL	30	91.73	12.774	

Systolic Blood Pressure

	Group	No	Mean	SD	P Value
Pre Insertion	I GEL	30	122.40	12.036	P=0.790 Not Significant
	PRO SEAL	30	121.63	10.128	
Post Insertion after 1 min	I GEL	30	122.97	12.019	P=0.382 Not Significant
	PRO SEAL	30	119.83	15.324	
Post Insertion after 5 min	I GEL	30	118.60	13.903	P=0.799 Not Significant
	PRO SEAL	30	119.50	13.292	

Diastolic Blood Pressure

	Group	No	Mean	SD	P Value
Pre Insertion	I GEL	30	80.93	8.416	P=0.817 Not Significant
	PRO SEAL	30	80.50	5.782	
Post Insertion after 1 min	I GEL	30	82.40	10.388	P=0.191 Not Significant
	PRO SEAL	30	77.43	17.751	
Post Insertion after 5 min	I GEL	30	77.23	12.356	P=0.313 Not Significant
	PRO SEAL	30	80.47	12.272	

Mean Arterial Pressure

	Group	No	Mean	SD	P Value
Pre Insertion	I GEL	30	94.27	8.702	P=0.906 Not Significant
	PRO SEAL	30	94.03	6.312	
Post Insertion after 1 min	I GEL	30	95.63	10.620	P=0.344 Not Significant
	PRO SEAL	30	92.80	12.310	
Post Insertion after 5 min	I GEL	30	90.67	12.347	P=0.419 Not Significant
	PRO SEAL	30	93.23	12.054	

Heart rate, Blood Pressure were measured preoperatively before insertion of airway devices and 1 min & 5 min after insertion. The actual value are documented in the tabular column.

Heart Rate

Mean Preinsertion Heart rate with I Gel Group is 89 and Pro Seal Group is 83.47. Mean Heart rate 1min after insertion with I Gel group is 95.4 and Pro Seal group is 92.6. Mean Heart Rate 5min after insertion with I Gel group is 93.6 and Pro Seal group is 98.7.

Statistical analysis reveals P Values of Pre insertion heart rate, Heart rate 1min after insertion & Heart rate 5min after insertion was 0.073, 0.353 & 0.527 respectively. These P Values are Statistically Not Significant.

Blood Pressure

P values of pre insertion systolic, diastolic, mean arterial pressure were 0.790, 0.817, 0.906 respectively. P values of systolic, diastolic, mean arterial pressures after 1 minute of insertion were 0.382,0.197,0.344 respectively. P values of systolic diastolic mean arterial pressure after 5 mintues of insertion were 0.799, 0.313, 0.419. respectively. These p values are statistically insignifigant.

DISCUSSION

The Pro Seal LMA provides an acceptable way to maintain a clear airway and provide positive pressure ventilation. It is also associated with reduced risk of gastric insufflations, Regurgitation & aspiration of gastric contents.

I Gel also provides patent airway during positive pressure ventilation. It is also reduces the risk of gastric insufflations, Regurgitation & aspiration of gastric contents.

This study was designed to compare clinical performance of this two Supraglottic airway devices I Gel & Pro Seal LMA. This study was conducted in 60 adult Women, ASA I & II, aged 18yrs & above undergoing elective Gynaecological surgeries.

1. EASE OF INSERTION

Ishwer singh and the Monika Gupta[1] compared IGEL and PLMA in 60 patients. They found ease of insertion was more with IGEL (29/30) then with LMA Proseal (23/30) which was statistically significant.

In my study the ease of insertion was more with IGEL (29/30) then with proseal LMA (22/30) P value is 0.038 which was statistically significant at 5% level.

Levitan & Kinkle[2] presumed that on insertion of LMA with inflatable mask, the deflated leading edge of the mask can catch the edge of the epiglottis & cause it to downfold or impede proper placement beneath the tongue. Brimacombe and colleagues[5] presumed that the difficulties by larger cuff impeding digital intraoral positioning and propulsion into the pharynx. The lack of back plate making cuff more likely to fold over at the back of the mouth and the need for more precise tip positioning to prevent air leaks up the drainage tube.

The finding of my study was in concurrence with the above data. So IGEL is easier to insert as compare to proseal LMA.

2. NUMBER OF ATTEMPTS

Ishwar singh and Monika Gupta[1] compared IGEL and proseal LMA in 60 patients they found first attempt success rate with IGEL (30/30) (100%) higher then with proseal LMA (28/30) (93.3) P value is < 0.05 so statistically insignificant.

In my study the first attempts success rate with IGEL was (28/30) (93.3%) with proseal LMA was (24/30) (80%) P value is 0.129 (P>0.05) this value or statistically insignificant.

The finding of my study was in concurrence with the above data. So number of attempt require for IGEL was fewer than that of proseal LMA.

3. TIME TAKEN FOR INSERTION

J.J. Gatward & T.M. Cook evaluated the size 4 IGEL airway in one hundred non paralyzed patient. In this study they found mean insertion time with IGEL was 15 sec.

In my study mean insertion time with IGEL was 16.2 sec, with proseal LMA was 25.2 sec P value is 0.000 which was significant at 1% level. The finding of study was in concurrence with above data. So insertion time with IGEL was shorter than proseal LMA.

4. HAEMODYNAMIC RESPONSE

SHIN WJ, & cheyng. YS[17] compared IGEL proseal LMA and classic LMA in elective surgery. They assessed haemodynamic response. In this study they found there is no difference in heamodynamic deference between IGEL, proseal LMA and classic LMA.

In my study also there is no difference in heamodynamic response between IGEL and proseal LMA.

The finding of my study was in concurrence with above data.

5. BLOOD STAINING OF DEVICE

In Ishwar singh and Monika Gupta[1] study blood staining of the devices with IGEL was 1/30, with proseal LMA was 6/30 P value is > 0.05 in my study blood staining of the devices with IGEL was 2/30 with proseal LMA was 8/30 P value is 0.038 which is statistically significant at 5% level.

In both study blood staining of devices with IGEL was lesser than proseal LMA so airway trauma was less with IGEL than proseal LMA.

6. INCIDENCE OF COMPLICATION

In Ishwar singh and Monika Gupta[1] study there was no incidence of sorethroat, bronchospasm, laryngospasm, Regurgitation in both groups.

But in my study there was a incidence of sorethroat in 2 cases with proseal LMA. No incidence of bronchospasm, laryngosmpasm, Regurgitaion with proseal LMA in IGEAL group there was no incidence of sorethroat, bronchospasm, laryngospasm, Regurgitation P value of sorethroat was 0.150 which was statistically not significant.

So incidence of complication with IGEL was comparatively less but statistically not significant.

SUMMARY

The Prospective Randomized comparative single blinded case control study of clinical performance of two Supraglottic airway devises IGel & Pro Seal LMA in 60 adult women, ASA I & II, aged 18 and above undergoing elective Gynaecological surgeries.

The conclusion deduced from the study are:

1) There were no significant difference between the two groups in demographic data

2) Ease of insertion of I Gel was better than that of Pro Seal LMA which is Statistically Significant at 5% level (P=0.038)

3) Number of attempts required for successful placement for I Gel were fewer than that of Pro Seal LMA but Not Statistically Significant.

4) Time taken for insertion of I Gel was lesser than Pro Seal LMA which is Statistically Significant at 1% level.

5) There is No Significant Haemodynamic changes between I Gel & Pro Seal groups.

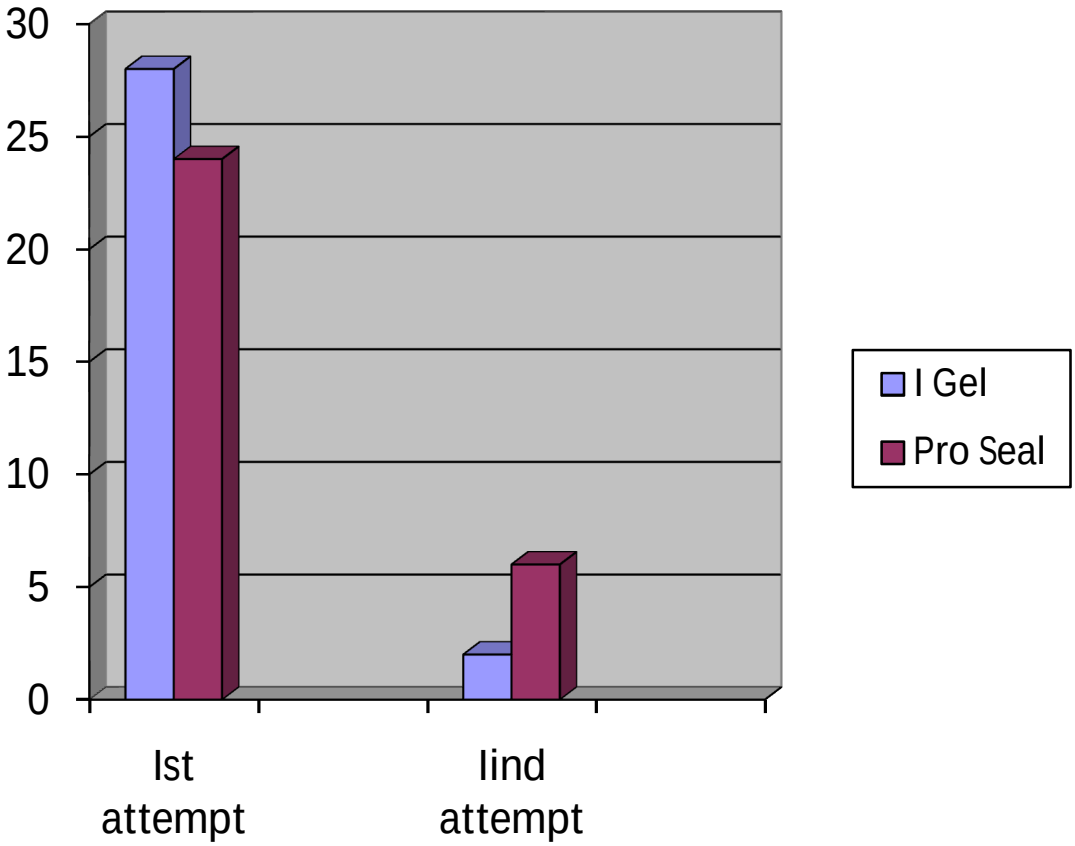
6) Blood staining of the devices with I Gel was fewer than Pro Seal LMA which is Statistically Significant at 5% level. So airway trauma was few with I Gel compared to Pro Seal LMA.

7) Incidence of Sore Throat was few with Pro Seal LMA but Sore Throat did not occur in I Gel. The other complications like Bronchospasm, Laryngospasm & Regurgitation did not occur in both groups.

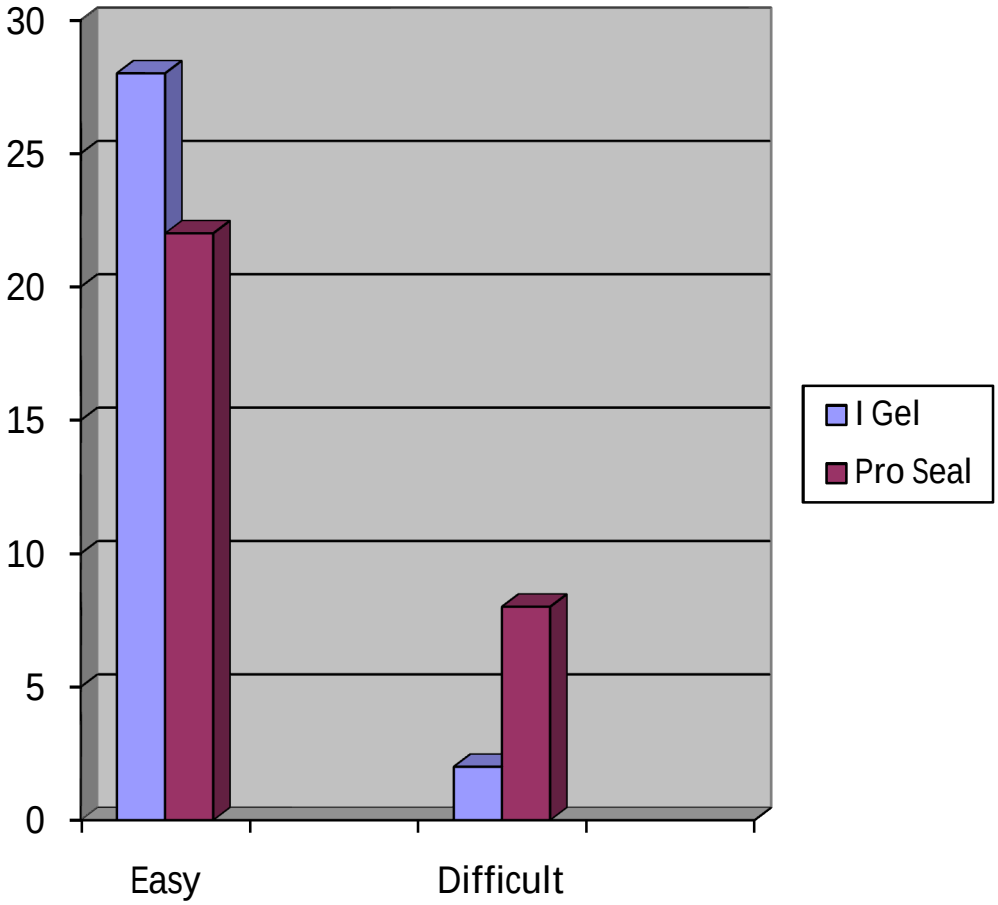
CONCLUSION

I Gel is a cheap and effective device which is easier to insert than Pro Seal LMA. It has other potential advantages like rapid placement, less blood staining, less airway trauma than Pro Seal LMA. So I Gel is a useful alternative Supraglottic device to Proseal LMA.

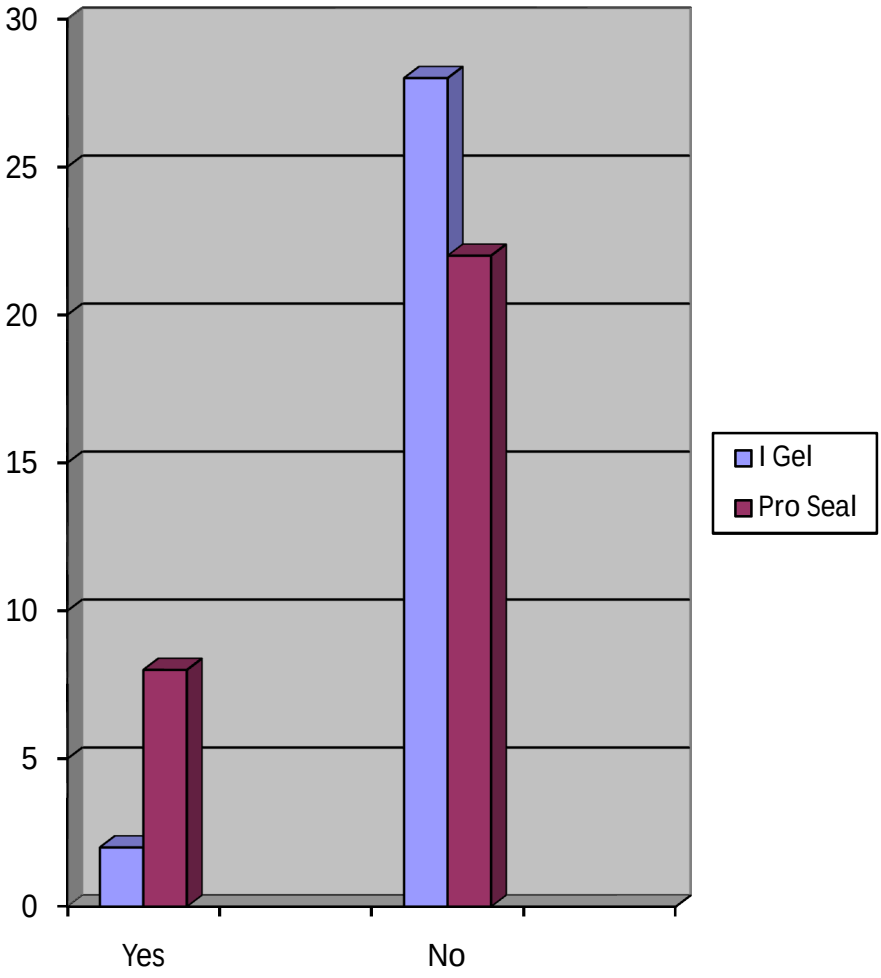
NUMBER OF ATTEMPTS



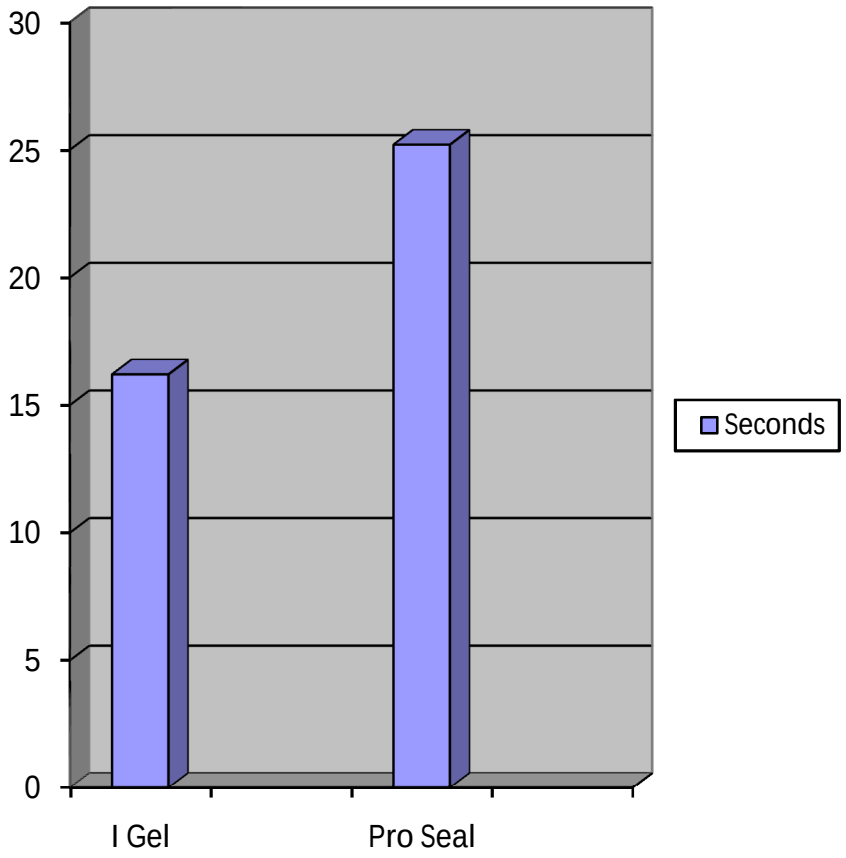
EASE OF INSERTION



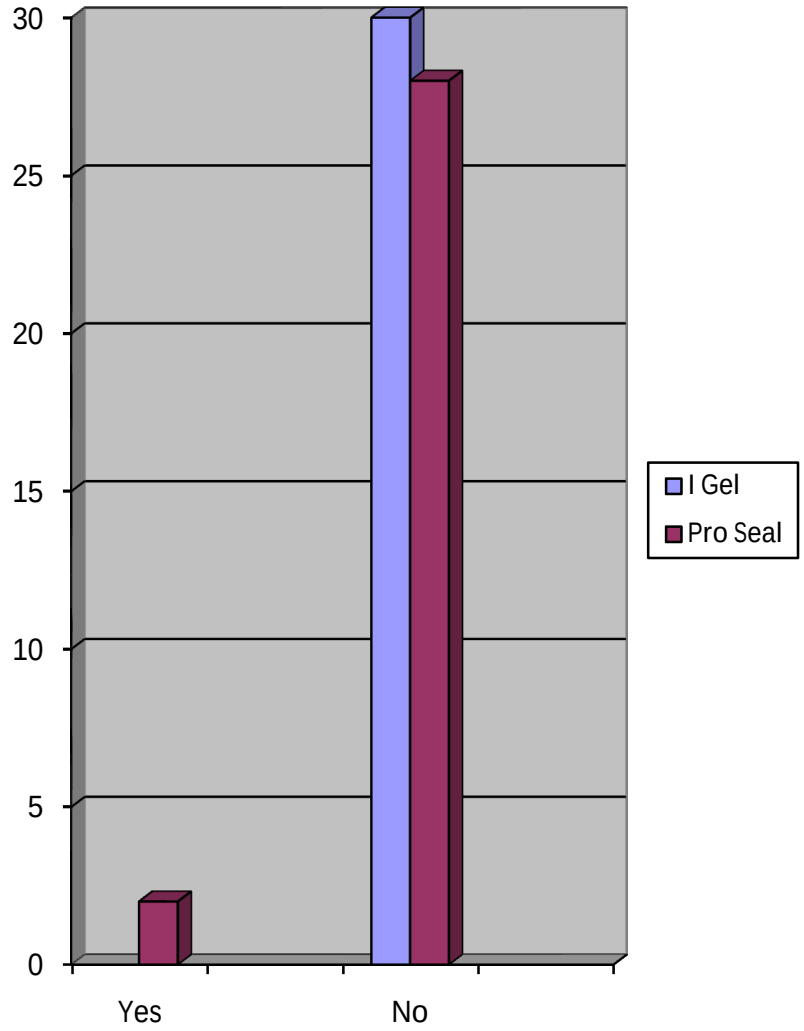
BLOOD STAINING OF DEVICE



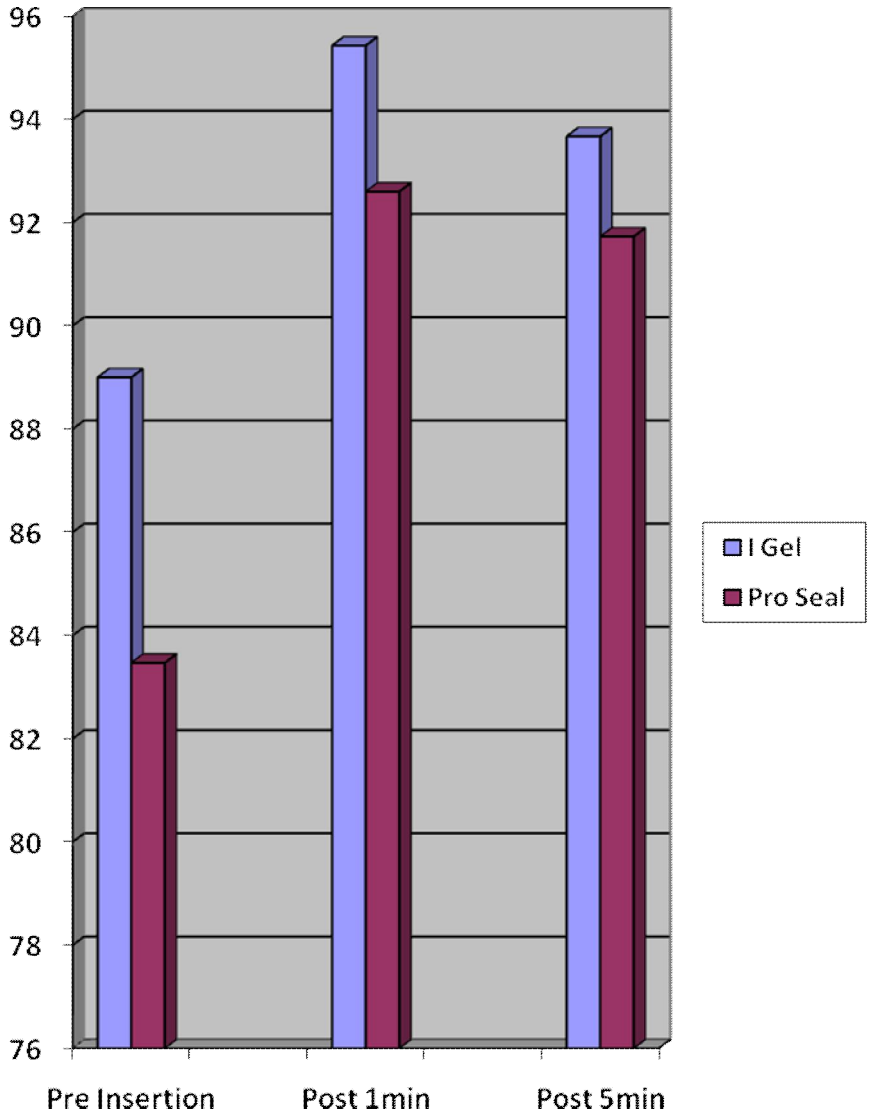
TIME TAKEN FOR INSERTION



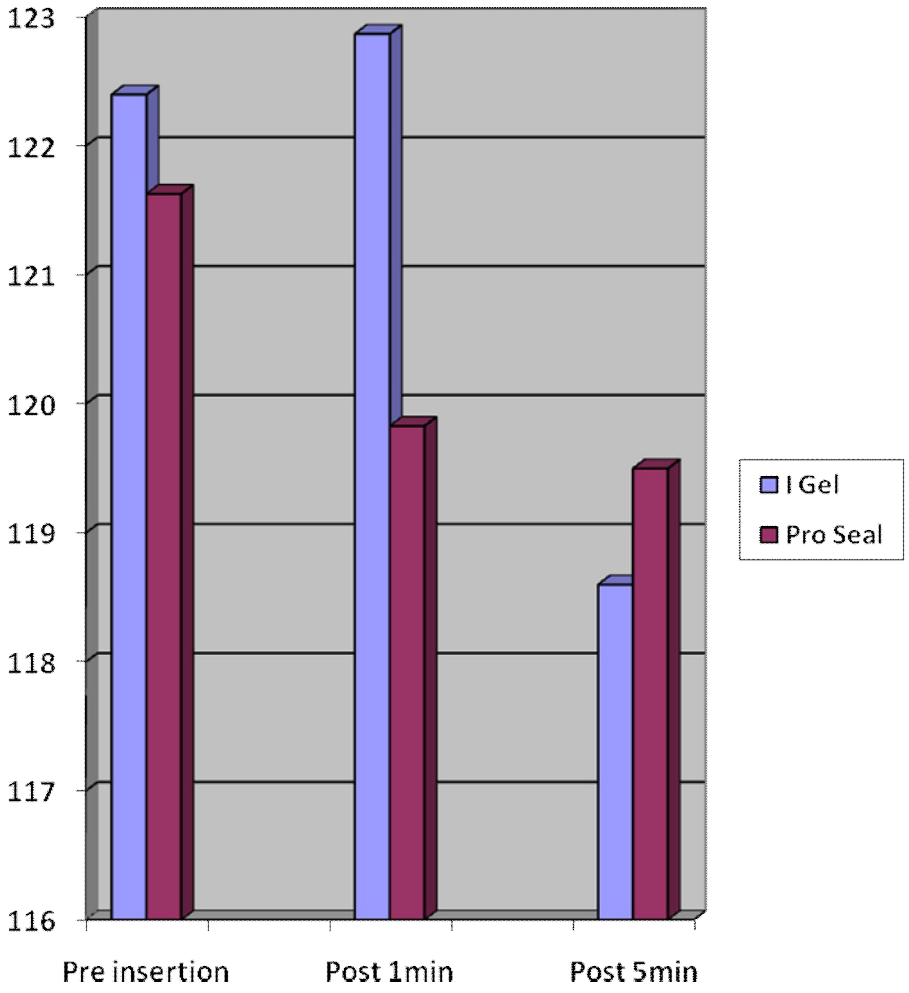
INCIDENCE OF SORE THROAT



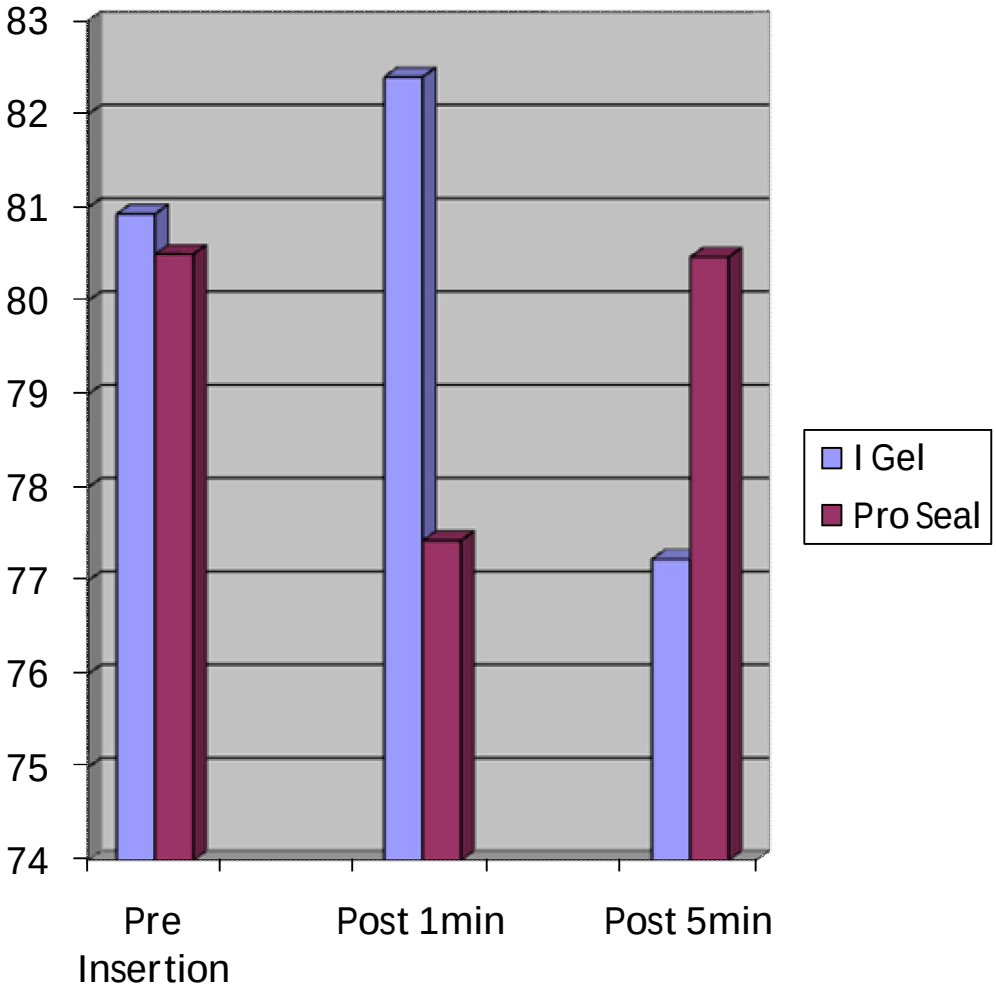
HEART RATE


96
94
92
90
88
86
84
82
80
78
76
Pre Insertion
Post 1min
Post 5min
I Gel
Pro Seal

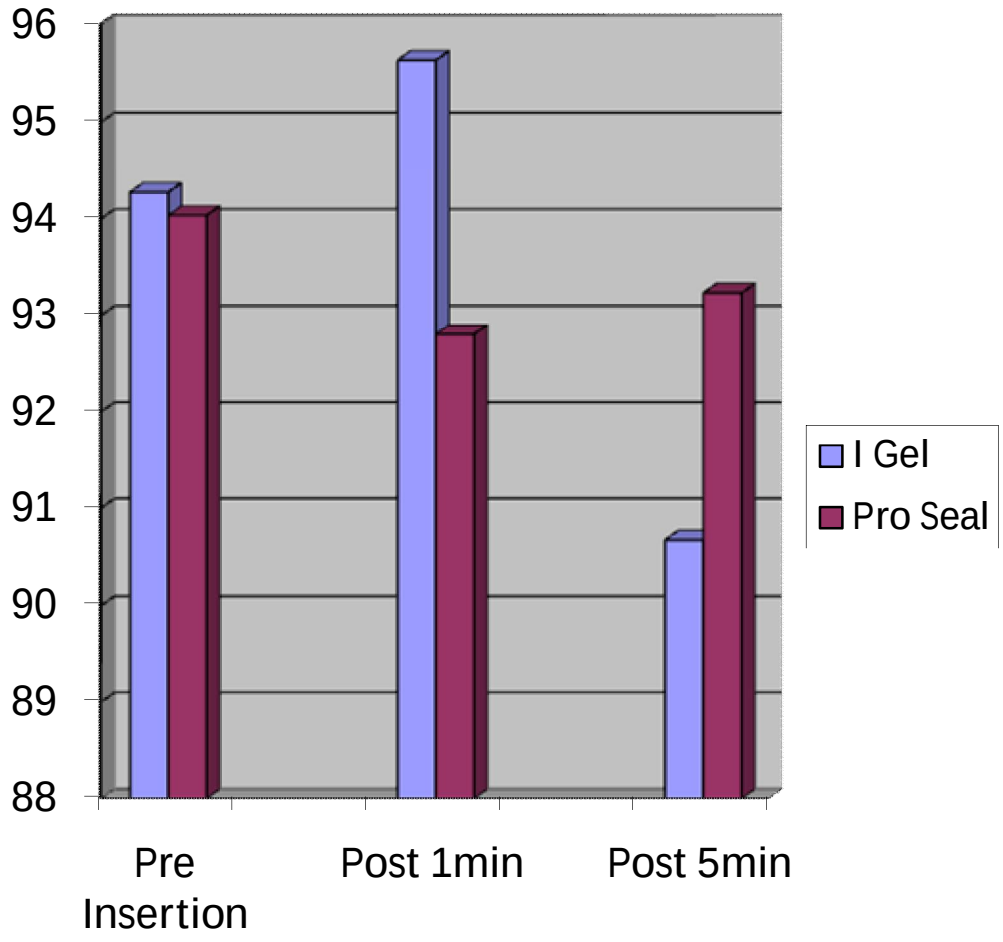
SYSTOLIC BLOOD PRESSURE



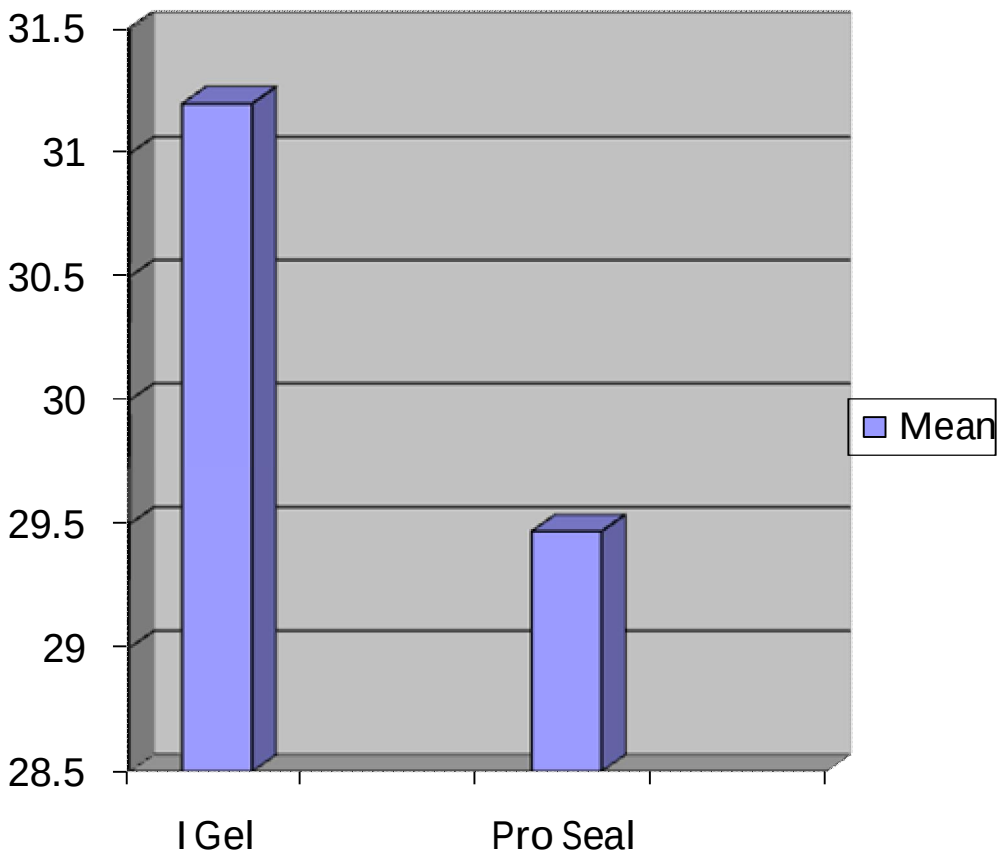
DIASTOLIC BLOOD PRESSURE



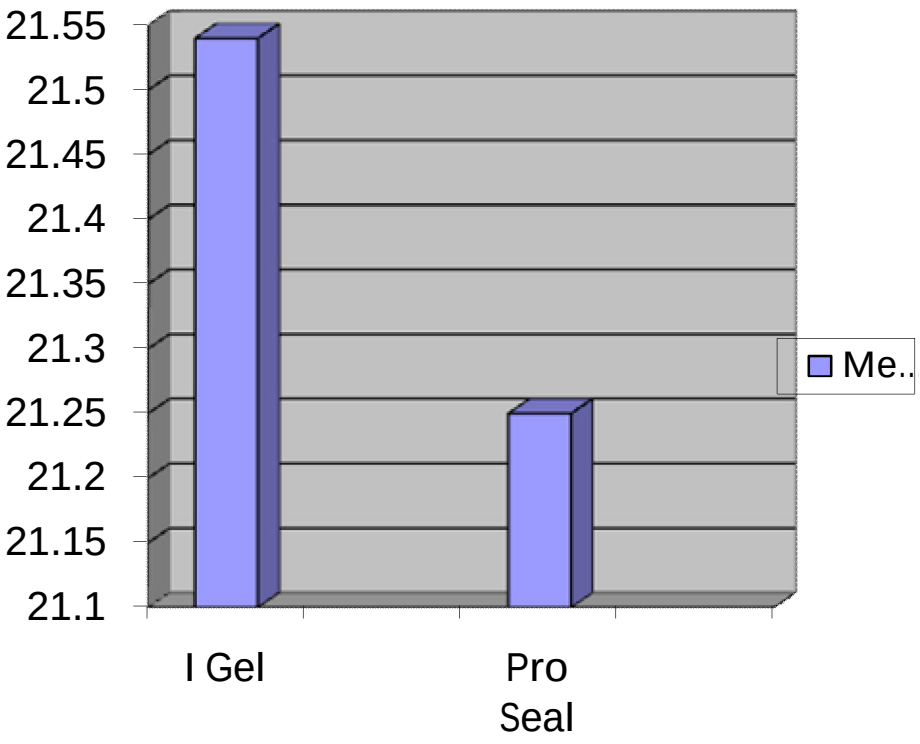
MEAN ARTERIAL PRESSURE



DEMOGRAPHIC PROFILE: AGE



DEMOGRAPHIC PROFILE: BMI



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PROFORMA

AIRWAY DEVICE USED : ……

NAME :

AGE :

IP No :

Wt : Ht : BMI :

Diagnosis :

Surgical Procedure Done :

PRE OPERATIVE ASSESSMENT

A. HISTORY

Co morbid illness and treatment details :

Effort Tolerance : …… METS

H/O any documented difficult Airway :

H/O Previous Surgeries

GENERAL EXAMINATION

Anemia : Jaundice :

BP : Pulse :

CVS : RS :

a. AIRWAY EXAMINATION

- Mallampatti Classification :
- Neck Flexion :
- Neck extension :
- Inter Incisor Distance : …….. cm
- Thyro Mental distance : …… cm
- Upper Lip Bite Test :

- Denture : YES / NO
- If yes it is removable / fixed :
- Buck teeth :
- Loose teeth :
- Absent teeth :

D. <u>MEASURES OF STUDY OUTCOMES</u> :

1. Ease of Insertion :

EASY	DIFFICULT

2. No. of Insertion attempts.

3. Time taken for Insertion.

4. Haemodynamic response.

	PRE INSERTION			POST INSERTION					
				After 1 minutes			After 5 minutes		
Blood Pressure	**SYS**	**DIA**	**MEAN**	**SYS**	**DIA**	**MEAN**	**SYS**	**DIA**	**MEAN**
Heart Rate									

5. Blood staining of device after removal Yes / No

6. Incidence of Complication :

B - Bronchospasm Yes / No

L - Laryngospasm. Yes / No

S - Sorethroat Yes / No

R - Regurgitation Yes / No

ABBREVIATION

LMA – Laryngeal mask airway

PLMA – Proseal Laryngeal mask airway

DT – Drainage tube

IPPV – Intermittent positive pressure ventilation

ID – Internal diameter

ETT – Endo tracheal tube

BMI – Body mass index

NIBP – Non invasive blood pressure

ECG – Electro cardiogram

EtCo2 – End tidal Co2

SD – Standard deviation

SLIPA – Streamlined liner of the Pharyngeal airway

PATIENT CONSENT FORM

STUDY TITLE: Prospective, randomiscd comparison study of clinical performance of two supraglottic ainvays, PROSEAL LMA and L-GEL in elective surgeries.

STUDY CENTRE : Department of Anaesihesiology, Institute of Obstetrics and Gynecology.

PARTICIPANT NAME : AGE: SEX: LD.NO:

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my stratification.

I have been explained about the possible complications that may occur during the procedure. Like injury to throat changes in voice, I understand that every precaution will be taken to prevent such as injury. If it happen will be treated accordingly. I have been informed that no other 'major complication has been reported so far with use of airway device PROSEAL LAM & I GEL

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to the current study -and any further research that may be conducted in relation to it, even if I withdraw fro m the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required the law. I agree not to restrict the use of any data or results that arise from the study.

I here consent to participate in this study of comparison study of clinical performance of two supraglottic airways, PROSEAL LMA and L-GEL in elective surgeries.

Time:

Date : Signature / Thumb impression of patient

Place: Patient Name:

Signature of the investigator : _____

Name of the investigator : _____

Í Â ´ ôÒ¾ø ÀÊÅõ

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ÁÂì¸õ ¦¸¡ Î ôÀ¾ü Ì ÀÂý À Î ò¾ôÀ Î õ þÕ Å¨¸Â¡É ¦À¡Õð¸Ç¡É **PROSEAL LMA**, ÁüÚõ **I-GEL** ¸ÕÅ¢¸Ç¢ø ±ó¾ ¸ÕÅ¢ ¯À§Â¡¸ôÀ Î òÐÅ¾ü Ì ±Ç¢¾¡¸ ¯ûÇÐ ±ýÀ¨¾ ¸ ñ ¼È¢Ôõ ¬ ö ×.

¬Ã¡öîº¢ ¿¢¨ ÄÂõ : ÁÂì¸Å¢Âø Ð¨È «ÃÍ Á¸ô§ÀÚ ÁÕòÐÅÁ¨É ±ì§Á¡÷, ¦ºý¨É.

Àí Ì ¦ÀÚÀÅ¡¢ý ¦ÀÂ÷ :

Àí Ì ¦ÀÚÀÅ¡¢ý ± ñ :

À¡Ä¢Éõ :

Àí Ì ¦ÀÚÀÅ÷ þ¾¨É (√) ÌÈ¢ì¸×õ.

§Á§Ä ÌÈ¢ôÀ¢¼ôÀð¼Î ûÇ ÁÕòÐÅ ¬ öÅ¢ý Å¢ÅÃí¸û ±É ì Ì Å¢Çì¸ôÀð¼Ð. ±ý Û¨¼Â ºó§¾¸í¸¨Ç §¸ð¸×õ, «¾ü¸¡É ¾Ì ó¾ Å¢Çì¸í¨Ç ¦ÀÈ×õ Å¡öôÀÇ¢ì¸ôÀð¼Ð.

¿¡ý þùÅ¡öÅ¢ø ¾ýÉ¢î¨ºÂ¡¸ò¾¡ý Àí§¸ü¸¢§Èý. ±ó¾ ¸¡Ã½ ò¾¢É¡§Ä¡ ±ó¾¸ð¼ò¾¢Öõ ±ó¾ ºð¼ º¢ì¸Öõ ¯ðÀ¼¡Áø ¿¡ý þùÅ¡öÅ¢ø þÕóÐ Å¢Ä¸¢ ¦¸¡ûÇÄ¡õ ±ýÚõ «È¢óÐ ¦¸¡ñ§¼ý.

þó¾ ¬ ö × ºõÀó¾Á¡¸§Å¡, þ¨¾ º¡÷ó¾ §ÁÖõ ¬ ö × §Áü¦¸¡û Ùõ §À¡Ðõ þó¾ ¬ öÅ¢ø Àí Ì ¦ÀÚõ ÁÕòÐÅ÷ ±ý Û¨¼Â ÁÕòÐÅ «È¢ì¨¸¸¨Ç À¡÷ôÀ¾ü Ì ±ý «ÛÁ¾¢

§¾ ¨ ÅÂ¢ø ¨ Ä ±É «È¢óÐ ¦¸¡û¸¢§È ý. ¿¡ý ¬öÅ¢ø þÕóÐ Å¢Ä¸¢ ¦¸¡ ñ ¼¡Öõ þÐ ¦À¡ÕóÐõ ±É «È¢¸¢§È ý.

þó¾ ¬öÅ¢ý ãÄõ ¸¢¨¼ì Ìõ ¾¸Åø¸¨ ÇÔõ, À¡¢§º¡¾¨ É ÓÊ×¸¨ ÇÔõ ÁüÚõ º¢¸¢î¨º ¦¾¡¼÷À¡ É ¾¸Åø¸¨ ÇÔõ ÁÕòÐÅ÷ §Áü¦¸¡û Ùõ ¬öÅ¢ø ÀÂýÀÎò¾¢ì ¦¸¡ûÇ×õ «¨¾ À¢ÃÍ¡¢ì¸×õ ±ý ÓØ ÁÉÐ¼ý ºõÁ¾¢ì¸¢§È ý.

þó¾ ¬öÅ¢ø ¸ÕÅ¢¸¨Ç ÀÂýÀÎòÐõ§À¡Ð ¦¾¡ ñ ¨¼Â¢ø ¸¡Âõ, Á÷Úõ ÌÃÄ¢ø Á¡üÈõ ²üÀÎÅ¾üÌ Å¡öôÒ¸û ¯ûÇÐ ±ýÚõ, «¾üÌ ¾ì¸ ¿¼ÅÊì¨¸ ±Îì¸ôÀÎõ ±ýÀ¨¾Ôõ ÁÕòÐÅ÷ ãÄõ «È¢óÐ ¦¸¡ñÎ ¿¡ý þó¾ ¬öÅ¢ø Àíì¦ÀÈ ÓØÁÉÐ¼ý ºõÁ¾¢ì¸¢§È ý.

§¿Ãõ:
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ÁÂì¸õ ¦¸¡ Î ôÀ¾ü Ì þÕÅ¨¸Â¡ É ¸ÕÅ¢¸û PROSEAL LMA ÁüÚõ IGEL ¸ÕÅ¢¸û ¯À§Â¡¸ôÀ Î ò¾ôÀ Î ¸¢ÈÐ. þó¾ þÃ ñ Î ¸ÕÅ¢¸Ç¢ø ±ó¾ ¸ÕÅ¢ ¯À§Â¡¸ôÀ Î òÐÅ¾ü Ì ±Ç¢¾¡¸ ¯ûÇÐ ±ýÀ¨¾ì ¸ ñ¼È¢Â þó¾ ¬ ö × ¦ºöÂôÀ Î ¸¢ÈÐ. þó¾ ¸ÕÅ¢¸¨Ç ¯À§Â¡¸ôÀ Î òÐõ§À¡Ð ¦¾¡ ñ ¨¼Â¢ø ¸¡Âõ ÁüÚõ ÌÃÄ¢ø Á¡üÈõ ²üÀ Î Å¾ü Ì Å¡öôÒ¸û ¯ûÇÐ. «ôÀÊ §¿÷ó¾¡ø «¾ü Ì ¾ì¸ ¿¼ÅÊì¨ ¸ ± Î ì¸ôÀ Î õ. §ÁÖõ, þó¾ ¸ÕÅ¢¸¨Ç ¯À§Â¡¸ôÀ Î òÐÅ¾¡ø, ÀÂôÀ Î Å¾ü Ì È¢Â §ÅÚ ±ó¾ À¢ý Å¢¨Ç×¸Ù õ þø¨Ä. þó¾ Å¢ÅÃí¸¨Ç «È¢ó¾ ¿¡ý §Áü Ì È¢Â ¬ öÅ¢ø ÓØÁÉÐ¼ý Àí§¸ü¸ ºõÁ¾ì¸¢§Èý.

Àí Ì ¦ÀÚÀÅ¡¢ý ¨¸¦Â¡ôÀõ

þ¼Ð ¨¸¸ð¨¼ Å¢Ãø §Ã¨¸

¦ÀÂ÷:

INFORMATION ON THE STUDY

General Anesthesia can be administered through supraglottic airways. Comparison of ease of insertion of two supragottic airways. PROSEAL LMA and IGEL being studied. While using these airways there is chance of occurance of throat injury and hoarseness of voice. In case of such orrurance it will be treated accordingly. I have been informed that no other major complication has been reported so far with use of airway device proseal LMA and IGEL. Knowing this information, I consent to whole heartedly participate in the above study.

Patients Signature

Thumb Impression;

Name :

MASTER CHART

S.No	Name	Age	Device	BMI	EOI	NOA	TTI (Sec)	HEART RATE			BLOOD PRESSURE									Blood Stain	COMPLICATION			
											PRE INSERTION			POST INSERTATION										
								Pre	Post 1 Min	Post 5 Min	Sys	Dia	Mean	Sys	Dia	Mean	Sys	Dia	Mean		BS	LS	ST	RN
1	RANI	30	IGEL	19.0	E	1	15	91	94	94	121	81	94	128	90	102	118	81	93	No	No	No	No	No
2	SHAHEENA	25	IGEL	25.0	E	1	18	96	101	90	123	78	93	130	82	98	123	70	87	No	No	No	No	No
3	KAVITHA	27	IGEL	20.0	E	1	20	86	91	93	122	82	95	121	91	101	108	74	85	No	No	No	No	No
4	AMUDHA	25	IGEL	22.1	E	1	20	94	100	85	128	86	100	133	94	107	133	99	110	No	No	No	No	No
5	B B JOHN	46	IGEL	22.1	E	1	20	60	67	72	124	83	96	129	82	97	115	82	93	No	No	No	No	No
6	VALLI	19	IGEL	21.4	D	2	26	91	94	95	119	74	89	107	64	78	116	62	80	Yes	No	No	No	No
7	ROSI	46	IGEL	23.1	E	1	20	85	90	77	127	85	99	106	70	82	98	60	72	No	No	No	No	No
8	BRINDA	37	IGEL	26.0	E	1	15	80	90	84	120	82	94	129	90	103	109	69	82	No	No	No	No	No
9	SITA	40	IGEL	21.3	E	1	15	90	96	91	110	85	93	120	89	99	136	92	106	No	No	No	No	No
10	SUMITRA	28	IGEL	22.9	E	1	15	80	85	86	111	78	89	116	84	94	110	70	83	No	No	No	No	No
11	PRIYA	24	IGEL	23.1	E	1	15	100	110	113	111	71	84	117	75	89	118	72	87	No	No	No	No	No
12	RAMANI	26	IGEL	17.7	E	1	15	120	126	124	140	90	106	146	96	112	150	92	111	No	No	No	No	No
13	KANAGA	21	IGEL	24.4	E	1	16	93	101	99	123	80	94	128	88	102	105	58	73	No	No	No	No	No
14	VENI	45	IGEL	21.4	E	1	15	101	106	88	110	88	95	114	80	91	97	67	77	No	No	No	No	No
15	CHANDRA	40	IGEL	20.0	E	1	15	80	85	81	146	74	98	109	73	85	110	76	87	No	No	No	No	No
16	THILAGA	26	IGEL	21.3	E	1	15	92	100	102	115	80	91	120	83	95	107	67	80	No	No	No	No	No
17	RAJAMMAL	35	IGEL	22.2	E	1	15	96	100	102	130	86	97	136	92	106	140	102	114	No	No	No	No	No
18	VALLI	20	IGEL	17.7	E	1	15	92	98	100	106	64	78	96	52	66	105	63	77	No	No	No	No	No
19	MAHESWAR	28	IGEL	20.0	E	1	15	92	100	104	102	60	74	109	72	84	116	80	92	No	No	No	No	No
20	INDUMATH	30	IGEL	23.1	E	1	14	82	85	86	149	105	119	126	80	95	120	76	90	No	No	No	No	No
21	GEETHA	41	IGEL	22.2	E	1	18	90	96	101	120	82	94	126	90	102	127	93	104	No	No	No	No	No
22	INDRA	46	IGEL	22.2	E	1	20	85	92	90	110	76	87	116	73	87	105	68	80	No	No	No	No	No
23	KARTHIKA	19	IGEL	20.4	E	1	12	72	78	82	120	84	96	126	88	100	130	86	100	No	No	No	No	No
24	ANANDHI	27	IGEL	24.4	D	2	25	82	92	96	110	76	84	124	86	98	130	90	103	Yes	No	No	No	No
25	RAMADEVI	19	IGEL	17.7	E	1	14	92	102	106	115	70	85	125	76	92	113	62	79	No	No	No	No	No
26	SHAHEENA	22	IGEL	22.2	E	1	13	96	101	93	140	85	103	146	92	110	120	70	86	No	No	No	No	No
27	VASANTHA	48	IGEL	22.2	E	1	12	86	96	95	140	84	102	120	76	90	130	85	100	No	No	No	No	No
28	SUNDARI	40	IGEL	20.0	E	1	13	92	97	91	124	85	98	110	74	86	98	70	79	No	No	No	No	No
29	KALLI	30	IGEL	21.3	E	1	13	92	100	101	136	90	105	146	98	114	145	93	110	No	No	No	No	No
30	MEENA	26	IGEL	20.0	E	1	12	82	90	89	120	84	96	130	92	104	126	88	100	No	No	No	No	No

S.No	Name	Age	Device	BMI	EOI	NOA	TTI (Sec)	HEART RATE			BLOOD PRESSURE									Blood Stain	COMPLICATION			
											PRE INSERTION			POST INSERTATION										
								Pre	Post 1 Min	Post 5 Min	Sys	Dia	Mean	Sys	Dia	Mean	Sys	Dia	Mean		BS	LS	ST	RN
1	GOWRI	29	Proseal	21.3	E	1	27	79	91	79	123	84	97	128	91	103	136	98	110	Yes	No	No	Yes	No
2	CHINNAPO	46	Proseal	22.2	D	2	32	86	92	96	128	76	93	110	70	83	123	82	95	No	No	No	No	No
3	SHANTHI	49	Proseal	22.2	E	1	25	90	98	87	112	74	86	100	64	72	97	60	72	No	No	No	No	No
4	RAMAJAYA	19	Proseal	20.0	E	1	28	100	112	115	100	60	73	109	52	68	114	62	80	No	No	No	No	No
5	CHITRA	25	Proseal	21.4	E	1	25	112	122	126	116	80	92	107	72	83	104	65	78	No	No	No	No	No
6	KARPAGAM	43	Proseal	19.5	D	2	30	72	80	87	112	74	86	120	86	97	123	87	99	Yes	No	No	No	No
7	GRACE	20	Proseal	20.0	D	2	32	103	112	105	120	80	93	130	90	103	132	86	101	Yes	No	No	No	No
8	BHAVANI	41	Proseal	22.9	D	2	32	120	130	118	144	84	104	150	92	111	138	99	112	Yes	No	No	No	No
9	VALLI	43	Proseal	23.1	E	1	20	79	86	73	120	76	90	90	57	68	95	59	71	No	No	No	No	No
10	RANI	27	Proseal	19.5	E	1	25	78	88	92	110	86	94	94	78	83	106	83	90	Yes	No	No	Yes	No
11	RAJI	25	Proseal	20.8	E	1	22	65	75	78	124	83	96	120	60	80	106	58	74	No	No	No	No	No
12	SUDHA	26	Proseal	21.3	E	1	25	78	88	90	121	80	94	124	88	100	114	77	89	No	No	No	No	No
13	MEENA	19	Proseal	20.0	E	1	22	86	94	100	110	80	90	116	90	99	120	86	97	No	No	No	No	No
14	ANANDHI	36	Proseal	22.2	D	2	32	72	85	80	140	88	105	130	76	94	105	72	83	No	No	No	No	No
15	SAVITHA	27	Proseal	21.7	E	1	25	90	98	96	130	84	99	140	92	108	136	88	104	No	No	No	No	No
16	VALLI	19	Proseal	17.7	E	1	25	72	80	86	110	82	91	106	80	88	120	92	101	No	No	No	No	No
17	NEELAVEN	38	Proseal	22.2	E	1	25	78	87	89	120	86	97	130	90	101	130	96	107	No	No	No	No	No
18	SUGUNA	30	Proseal	20.0	D	2	35	78	92	96	120	84	96	130	92	104	136	90	105	Yes	No	No	No	No
19	KANNIMAR	30	Proseal	23.1	E	1	22	84	92	96	124	80	94	136	90	105	130	94	106	No	No	No	No	No
20	LAKSMI	28	Proseal	24.0	E	1	19	76	83	79	124	82	96	110	70	83	109	66	80	No	No	No	No	No
21	ARULMARY	23	Proseal	21.7	E	1	22	82	90	94	130	90	103	110	80	90	107	64	78	No	No	No	No	No
22	SUMATHY	30	Proseal	22.2	E	1	22	86	92	90	126	80	95	110	76	87	116	80	92	No	No	No	No	No
23	JENNIFER	22	Proseal	21.3	E	1	25	92	99	100	132	72	92	130	80	96	136	84	101	No	No	No	No	No
24	SUMATHY	28	Proseal	19.5	D	1	32	76	88	80	123	84	97	126	90	102	134	86	102	Yes	No	No	No	No
25	CHANDRA	24	Proseal	21.7	E	1	19	65	77	74	116	82	93	107	74	84	114	80	91	No	No	No	No	No
26	SARALA	42	Proseal	22.2	E	1	22	79	89	84	140	82	101	146	92	110	136	84	101	No	No	No	No	No
27	AMUDHA	22	Proseal	20.0	D	1	24	66	72	79	110	80	90	116	86	96	106	74	84	No	No	No	No	No
28	KARPAGAM	25	Proseal	23.1	E	1	20	74	86	85	120	84	96	130	90	103	130	96	107	Yes	No	No	No	No
29	SELVI	22	Proseal	21.4	E	1	22	92	100	102	112	74	86	100	69	79	106	80	88	No	No	No	No	No
30	KAVITHA	26	Proseal	19.5	E	1	20	94	100	96	132	84	102	140	6	104	126	86	99	No	No	No	No	No